

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,)	
)	
Plaintiff,)	
)	Criminal Action
v.)	No. 09-10330-GAO
)	
STRYKER BIOTECH, LLC,)	
et al.,)	
)	
Defendants.)	
)	

BEFORE THE HONORABLE GEORGE A. O'TOOLE, JR.
UNITED STATES DISTRICT JUDGE

**DAY FIVE
JURY TRIAL**

John J. Moakley United States Courthouse
Courtroom No. 9
One Courthouse Way
Boston, Massachusetts 02210
Friday, January 13, 2012
9:07 a.m.

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One Courthouse Way, Room 3510
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Mechanical Steno - Computer-Aided Transcript

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WITNESSES FOR THE
GOVERNMENT:

By Mr. Sternberg 62

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No. 12	Email from Houghton to Ring	119
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1 (The following proceedings were held in open court
2 before the Honorable George A. O'Toole, Jr., United States
3 District Judge, United States District Court, District of
4 Massachusetts, at the John J. Moakley United States Courthouse,
5 One Courthouse Way, Boston, Massachusetts, on January 13, 2012.

6 The defendants, William Heppner, David Ard and Jeffrey
7 Whitaker, are present with counsel. Assistant U.S. Attorneys
8 Jeremy Sternberg, Susan Winkler and Gregory Noonan are
9 present.)

00:24 10 THE CLERK: All rise.

11 (The Court enters the courtroom at 9:07 a.m.)

12 THE COURT: Good morning.

13 COUNSEL IN UNISON: Good morning, your Honor.

14 THE COURT: You heard about the issue with Juror No.
15 1, I gather?

16 MR. NOONAN: Yes, your Honor.

17 THE COURT: Just to recap it, he had told us during
18 the selection that his wife had an appointment that he would
19 like to accompany her to. And he told us at the time that it
00:31 20 was Monday, which is a scheduled holiday, so we didn't think
21 there was an issue. He brought in his actual form, and it
22 turned out they had the dates confused and it is Tuesday.

23 He has two -- there are two appointments: One is
24 Tuesday morning at 9:45. There's another one the following
25 Tuesday, but that's at three o'clock. I have a copy of the

1 appointment card for that. And so the problem is Tuesday
2 morning.

3 I think Paul notified counsel yesterday of the issue
4 and asked you to think about it. And it seems to me there were
5 two options: One is to excuse the juror -- well, there are
6 three options: One is to make him miss his appointment with
7 his wife, which I think is not a viable one; the other is to
8 excuse him and proceed; and the final one would be to just
9 skip -- Monday is a holiday. Just skip Tuesday and proceed to
00:32 10 reconvene on Wednesday.

11 So what is the view of counsel?

12 MR. NOONAN: Well, your Honor, the government believes
13 while it's obviously unfortunate to skip a day, and we're all
14 eager to get into this trial, the government thinks it's
15 awfully early to being excusing a juror in a long winter trial.
16 And we also don't want to encourage other people on the jury by
17 seeing someone go permanently at this stage.

18 So we think -- it's one day. We think the best course
19 is to take Tuesday off and carry on from there.

00:32 20 MR. LEVY: Your Honor, if I may, we had a chance,
21 defense counsel, to speak, and I'll speak on behalf of the
22 group. It's a tough decision. You know, I think this juror is
23 not terribly excited to be on jury duty. He did try a couple
24 of times with some problems. And I think it's related to his
25 wife's health. She's on a breathing machine. And while we

1 don't want to lose jurors either, we also are eager to get
2 going on this trial. We have scheduling issues on the back end
3 we've raised with the Court about expert witnesses we have.
4 And we're concerned about losing another day of trial.

5 You know, obviously, the Court has much more
6 experience with your rate of attrition with alternates. We
7 have three more. And, you know, I think the winter issues will
8 affect us all equally, so I don't think that will cause us to
9 lose jurors, in particular. It's another fact we have of
00:33 10 potentially more days off.

11 So our collective position is that we would excuse
12 this juror, albeit reluctantly, but keep moving ahead with the
13 trial and not be limited to three trial days next week.

14 THE COURT: One of the concerns is -- as Mr. Noonan
15 suggested, is the power of suggestion to the other jurors,
16 which is a concern.

17 MR. LEVY: It is a concern. All I can say is that
18 we'll have to take it on a case-by-case basis. I certainly
19 believed he had raised this issue, had the dates wrong. That's
00:34 20 a very natural thing to have happened. I don't think other
21 jurors are going to fabricate issues to get out of service at
22 this point.

23 THE COURT: One of the concerns implicit in what
24 you're saying is that it may not be that this is as limited a
25 problem to Tuesday morning as it might appear; in other words,

1 if his wife is suffering from some medical difficulties, that
2 will continue, and the question will be how much will that
3 affect -- I mean, we know that there's a particular time point
4 where we could solve it one way or the other.

5 I guess the question is what kind of betting that that
6 would be it.

7 MR. LEVY: Your Honor, you speak about the
8 distraction. That's a very good point. I'm also concerned two
9 medical appointments --

00:35 10 THE COURT: I'm not saying so much the distraction. I
11 think he could stay focused. I'm guess I'm just wondering if
12 it's just going to repeat.

13 MR. LEVY: Two appointments in a very short period of
14 time could very well lead to more follow-up, depending on
15 what's going on with her condition.

16 MR. NOONAN: Your Honor, the government's concern is
17 the primary suggestion to other jurors. Certainly, if after
18 one date this appears like it's going to be a continued issue
19 with the juror, at that point the government would take an
00:35 20 alternate position and we would have the alternate jurors at
21 that stage. The government position is that if we do it this
22 early on, when as of now his representation is he's going to
23 miss one day, we think we'll give him the one day. And if it
24 appears to be a problem after that, cut him loose.

25 THE COURT: Maybe we have to probe a little deeper

1 with him. I would prefer to do that in as low-key a way as
2 possible, and so I guess I would like to do it just myself, but
3 do it on the record.

4 MR. NOONAN: No objection from the government.

5 THE COURT: But just to see whether a one-time
6 accommodation would calm his anxieties or not.

7 MR. LEVY: Your Honor, we certainly don't object to
8 the Court doing it on its own. I do have concerns about losing
9 the trial date. We all have concerns about losing the trial
00:36 10 date -- we all are concerned about losing the trial day. The
11 inevitable January snow, February snow is going to come. I
12 think potentially we're looking at losing two or three days if
13 it's a normal winter -- it hasn't been so far -- but it's going
14 to add up. But I think we probably need more information to
15 make the final assessment.

16 THE COURT: All right. So we'll take a break, and
17 we'll have the reporter come back, and I'll talk to him and see
18 if I can get a sense as to whether a one-time accommodation
19 would solve the problem. I gather implicit in the government's
00:37 20 position is that -- one of the things I was thinking about is
21 you've got witnesses lined up and scheduled. You're willing to
22 deal with that issue, I guess?

23 MR. NOONAN: Yes, your Honor. If your Honor should
24 decide we'll take one day off, we have a few things we would
25 like to address with the Court, but we could wait until that

1 decision is made.

2 MR. O'CONNOR: Your Honor, one issue before the first
3 witness -- not before Mr. Libby speaks, but before the first
4 witness gets on we do have an important issue we want to raise
5 about the first witness. And so we could do it at sidebar but,
6 you know -- and I'm sure everyone's anxious to get going.

7 Well, are you proposing that you would talk to him
8 right now?

9 THE COURT: Yes.

00:37 10 MR. O'CONNOR: Before the jury comes in because I
11 don't want to suggest, your Honor, to come in and go out. I
12 know that takes time. But --

13 THE COURT: I'm not going to bring him into the
14 courtroom.

15 MR. O'CONNOR: I'm mixing things. Forgive me. We
16 have an issue we want to talk to you about that has to do with
17 the first witness, and I obviously don't want to do it in front
18 of the jury. I think it's better to do it in open court, but
19 we could do it at sidebar after Mr. Libby speaks or after
00:38 20 you're done with your discussion with the juror. Either way.

21 MR. NOONAN: Your Honor, the government has two
22 relatively brief issues we would like to --

23 THE COURT: I think what we'll do, let me talk to the
24 juror, I'll come out, tell you what I think we should do.

25 MR. O'CONNOR: Okay.

1 THE COURT: And then we could deal with these issues
2 and then we could call the jurors in.

3 MR. NOONAN: Thank you, your Honor.

4 THE CLERK: All rise. The Court will take a brief
5 recess.

6 (Lobby conference as follows:)

7 THE CLERK: Judge, I have Juror No. 1, Mr. Pomprowicz.

8 THE COURT: Good morning, Mr. Pomprowicz. Have a
9 seat; make yourself comfortable.

00:40 10 I just wanted to talk to you about your wife's
11 appointments and all. Let me tell you: We do not want you to
12 miss your wife's appointments.

13 JUROR NO. 1: Good.

14 THE COURT: Okay? All right. So it sort of gives us
15 a couple of options: One is we could just, as a trial, skip
16 Tuesday and have you go with your wife on Tuesday morning and
17 then the trial would resume on Wednesday. That would put
18 things back a little bit. The other would be, you know, we
19 could just excuse you and we'd just continue on without you.

00:40 20 I guess one of the things I'm interested in is --
21 without knowing in detail about the medical circumstances, is
22 this something that might recur over the next several weeks?
23 Will there be more appointments and things like that? That's
24 why I --

25 JUROR NO. 1: It depends on what they find in the CAT

1 scan. We have the follow-up the following Tuesday at three
2 o'clock in the afternoon. And we'll know from there if it's
3 something that needs to be addressed right away or months away.

4 THE COURT: What is it they're investigating for?

5 JUROR NO. 1: She has a growth in her lung. And they
6 wanted to do a CAT scan in December but they held off because
7 of the holidays. You don't want to ruin your holiday. So they
8 put it to January, and that's where it is now.

9 THE COURT: So they want to diagnose what that growth
00:41 10 is?

11 JUROR NO. 1: Right.

12 THE COURT: And I guess --

13 JUROR NO. 1: I have no idea. It could be -- maybe it
14 stays the same, maybe it's something that needs to be addressed
15 right away. I have no idea.

16 THE COURT: Yeah. Now, the appointment is at an MRI
17 or CT scan facility, I guess. And then the appointment the
18 following week is at the doctor's office. Is that it?

19 JUROR NO. 1: Yes.

00:41 20 THE COURT: That's in the afternoon. You would be
21 able to leave here at one and be there at three?

22 JUROR NO. 1: No, I have to leave here quarter to
23 twelve to get home to get her there at three. The train don't
24 leave till ten past twelve.

25 THE COURT: Oh, because of the train schedule?

1 JUROR NO. 1: Yes.

2 THE COURT: And you're taking the train rather than
3 driving?

4 JUROR NO. 1: Yes. I'm not familiar with this area.

5 THE COURT: So you think by the train schedule the
6 following Tuesday you would have to leave at --

7 JUROR NO. 1: Quarter to twelve.

8 THE COURT: -- quarter to twelve? Okay.

9 The other question, which is probably hard for you to
00:42 10 answer because it's asking you to speculate about the future,
11 when somebody close to you like this is undergoing these kinds
12 of things people can, you know, obviously be concerned about
13 them. And one question would be how much you might or might
14 not be distracted from the issues in the trial by the --

15 JUROR NO. 1: Because I don't know what the outcome
16 would be and I don't know -- I'm sure it would be weighing on
17 my mind. Somebody talks a long time and I can focus for the
18 whole hour and a half they're talking but -- you know, to
19 follow them, but I know -- it depends on the outcome. If
00:43 20 nothing happened, then I'm okay.

21 THE COURT: Then you'd be fine?

22 JUROR NO. 1: Yeah.

23 THE COURT: Let me ask you this: Have you mentioned
24 any of this to any of the other jurors?

25 JUROR NO. 1: No.

1 THE COURT: Okay. Is there anything else you think I
2 should know that I haven't asked you about?

3 JUROR NO. 1: No.

4 THE COURT: Okay. Thanks. I still have to talk about
5 it with the lawyers, and we'll decide what to do.

6 JUROR NO. 1: Okay. Thank you.

7 (Lobby conference concluded and in open court:)

8 THE CLERK: All rise.

9 (The Court enters the courtroom at 9:27 a.m.)

00:50 10 THE COURT: Be seated.

11 I've talked with the juror. Paul, can you sit down
12 for a minute, please -- thank you -- so I can see?

13 So I've talked to the juror. One thing respects next
14 Tuesday, and that is, apparently, the juror lives in
15 southeastern Massachusetts and has been taking the train up.
16 And in order to get back and get his wife and get to the three
17 o'clock appointment, he says he would have to catch a train
18 that would require him to leave here by about a quarter to
19 twelve. So it's not just the one day; it would be eating into
00:51 20 another half day.

21 It's very difficult to predict how people will respond
22 to things, but I did ask him whether he thought that -- and let
23 me just briefly -- as I understand, the medical issue is his
24 wife is having a diagnostic CT scan. That's this-coming
25 Tuesday. And then the following Tuesday is meeting with the

1 doctor to find out the results of that. And so there's a
2 medical diagnosis which is uncertain at this time. It could be
3 entirely benign, it could be a problem, and there's no way of
4 assessing that.

5 I think it likely from talking to him that if it
6 turned out to be anything other than totally benign, he would
7 be seriously distracted here. So I think -- it's a hard call
8 and I don't like doing it, but I think the better course is to
9 excuse him. I just can see it being a continuing management
00:52 10 problem. And I am concerned about the effect that that might
11 have on other jurors if it develops and goes along that way.

12 We do have -- the reason we do four, I guess -- as I
13 say, this is reluctant -- but I think it's probably the better
14 course. I'm not sure -- put another way, I'm not sure we would
15 have solved the problem if we just skipped the problem.

16 So my proposal to try to minimize the impact on the
17 other jurors is simply to have the juror sit through today.
18 We'll communicate privately with him that he's excused. And
19 when the other jurors return on Tuesday, he just won't be here,
00:53 20 and we'll just -- rather than dramatically excuse him now and
21 create any suggestion.

22 MR. LEVY: That's fine with the defense, your Honor.

23 MR. NOONAN: Fine, your Honor.

24 THE COURT: Okay. So, Mr. Noonan?

25 MR. NOONAN: A few brief issues on behalf of the

1 government. First, yesterday Mr. O'Connor opened on many
2 things, but also on the fact that there were some unindicted
3 coconspirators in this case, named two in particular,
4 Mr. Murphy and I believe Mr. Denney, and referred to other
5 unindicted coconspirator sales representatives. And he
6 specifically mentioned -- I don't have the transcript --
7 specifically mentioned these people are not being prosecuted by
8 the United States.

9 Now, the government is not trying to reargue your
00:54 10 Honor's immunity order, but we would like the unindicted
11 coconspirators who have immunity orders in this case who are
12 called as witnesses -- we think the door's been opened. This
13 may be overlapping. This might be people the defense planned
14 on impeaching with immunity orders. We don't know. We think
15 the door's been open, and right now the jury is going to think
16 there's a group of people who simply aren't being prosecuted by
17 the government when, in reality, they have an immunity order,
18 they were compelled in exchange for them not being prosecuted
19 by the government.

00:54 20 MR. O'CONNOR: Your Honor, one, I'm not sure I follow
21 the logic of -- to the extent that we said, as the Court
22 allowed, that the government has identified some people as
23 unindicted coconspirators that, therefore, they ought to be
24 able to put in front of the jury that these people have been
25 immunized unless -- if the defense is willing to commit not to

1 impeach them with that. So I just don't follow -- I don't
2 follow that logic.

3 I have not had a chance to speak with any of the other
4 defense lawyers, you know, about this issue. I do think, your
5 Honor, as we discuss -- we're going to go person by person. I
6 do think that judgments will be made. Yes, we would like to
7 impeach, and we will tell the government ahead of time, and
8 they can put it in on a case-by-case basis.

9 THE COURT: Well, let me just -- Mr. Ullmann?

00:55 10 MR. ULLMANN: If the door was opened -- I agree with
11 Mr. O'Connor. I don't follow the logic, but if the door was
12 opened, it was opened for two individuals: Mr. Murphy and
13 Mr. Denney. We might well want to impeach them. And if that
14 is the case the issue is moot. So I don't see any need to
15 discuss it further at this point.

16 THE COURT: Well, I'm not sure that the issue is
17 simply the question of impeachment by the immunity orders. I
18 think ordinarily it's not germane to the issues of the trial to
19 point out the government's prosecution strategy, why it
00:56 20 prosecutes some people and not others, for example.

21 The characterization of someone as an unindicted
22 coconspirator by the government might be done in order to have
23 advantage of the hearsay rules that would allow their
24 statements to be admitted. And if that's the case, then, of
25 course, the fact that they are alleged by the government to be

1 unindicted coconspirators is necessary to present so that the
2 jury can consider, among other things, *Petrozziello* factors.

3 In the absence of that, if they're just plain
4 witnesses and they're not going to be impeached by immunity,
5 then it would seem to me that there would be no reason for the
6 jurors to have them characterized; that is, if the government
7 doesn't want to use them as coconspirators for hearsay
8 purposes, and the defense doesn't want to accuse them by
9 impeachment through the immunity, then there would be no reason
00:57 10 for the jury to do it.

11 So I'm not sure what the respective strategies are
12 with respect to the witnesses. I mean, they've already now
13 been referred to in that characterization, but it seems to me
14 that there are limits as to why that should happen on both
15 sides.

16 MR. NOONAN: Agreed, your Honor. But -- and I'll get
17 the transcript. My recollection is Mr. O'Connor specifically
18 said, especially as to Mr. Murphy and Mr. Denney, unindicted
19 coconspirators who are not being prosecuted. That issue now is
00:57 20 alive. They've been told that and it will leave an improper
21 inference in the jury's mind. And I believe he made a broad
22 reference to other sales representative who are unindicted
23 coconspirators.

24 THE COURT: Well, let me ask this: The government
25 identified people, I guess, to the defense as unindicted

1 coconspirators.

2 MR. NOONAN: Yes, your Honor.

3 MR. O'CONNOR: Yes.

4 THE COURT: Why?

5 MR. NOONAN: For evidentiary reasons.

6 THE COURT: Okay. All right. So it's likely, then,
7 the government is going to want to characterize them as
8 coconspirators. I think it's fair for the defense, then, to
9 probe as to their status as possible biased witnesses for the
00:58 10 government because of promises or inducements or orders that
11 the government has obtained.

12 MR. NOONAN: Absolutely, your Honor. I completely
13 agree. At least with respect to the two individuals who are
14 named, Mr. Murphy and Mr. Denney, the government's position is
15 that they've already been, in some way, impeached. So we
16 should be able to lead off their directs, should we choose,
17 with directly bringing up their immunity orders.

18 MR. O'CONNOR: Your Honor, I'm not sure I follow the
19 logic. And they say they told us, you know, just for
00:58 20 evidentiary reasons. But they've indicted a conspiracy and
21 they've said that, you know, the company's part of that and
22 these people are the coconspirators. So I don't see any
23 problem with what I said -- at least, you know, certainly with
24 respect to the sales representatives in the opening.

25 We have to deal with a criminal charge. And the

1 criminal charge is that these people were involved in a
2 conspiracy. And it either makes sense or it doesn't, and we
3 think it doesn't. So I think it's okay to point that out.

4 On the theory, you know, that we said that they're not
5 being prosecuted -- and this is the two, Murphy and Denney -- I
6 don't see the logic for why the government ought to be able to
7 put down in front of the jury that they've been immunized
8 unless we're going to cross, because these people are senior
9 managers too. They are at the level of Mr. Whitaker --

00:59 10 THE COURT: Well, I think the point is that in a sense
11 they've already been impeached by the characterization in the
12 opening, and that's enough. I agree with the government on
13 that.

14 MR. NOONAN: Thank you, your Honor.

15 MR. O'CONNOR: Your Honor, on those two, right?

16 THE COURT: On those two.

17 You had something or --

18 MR. O'CONNOR: Yes, I do. Are you done?

19 MR. NOONAN: I have a logistical matter, but if yours
01:00 20 is more substantive.

21 MR. O'CONNOR: Yes, your Honor, this is substantive.
22 And this is important from our perspective, and it goes to --
23 we made a motion in limine with respect to -- I would like to
24 hand up -- I know the government has it -- and then ask you to
25 hand it down because I need it. But this is the so-called

1 Houghton slide deck and the consequences of off-label promotion
2 slide.

3 And I want to say this, your Honor: Our fears with
4 respect to what the government's trying to do here were
5 well-founded, as demonstrated by Ms. Winkler's opening. I'm
6 just going to read a few -- we have eight statements
7 where -- I'm going to read the first one. You'll see that
8 she's holding PowerPoint presentations that "They," the
9 defendants, "were actually trained that it was illegal and that
01:00 10 they should stop."

11 Second: "They were also told that it was illegal,
12 that it was criminal, and that it was a serious offense" -- you
13 can see the slide -- "if they did those things."

14 Third: "They also knew that promoting the mixture of
15 Calstrux and OP-1 to doctors was illegal."

16 Fourth: "Now, the evidence that you're going to hear
17 is that all of these defendants knew that promoting the mixture
18 of OP-1 and Calstrux to doctors was illegal."

19 That is what we were afraid -- and its first witness
01:01 20 is the guy on the slide. So their case is to charge felony
21 misbranding with intent to defraud or mislead, and also felony
22 fraud conspiracy and wire fraud. And they're going to try to
23 persuade the jury that pure, honest, truthful, off-label
24 promotion, if it occurred, is what's charged in the indictment
25 and that they ought to convict on it.

1 John Houghton and anyone else who had to do with that
2 slide, not a lawyer, not a judge. This jury needs to
3 understand what -- at a minimum, you know, what the law really
4 is if -- they're going to play it out the way Ms. Winkler did
5 in her opening and the way they're going to do it, trust me on
6 this, in the direct of Mr. Houghton. And so we ask that
7 the -- again, we renew our request that the slide either -- you
8 know, that it be excluded.

9 In the alternative, your Honor, we would like an
01:02 10 instruction before Mr. Houghton gets on the stand on these
11 legal principles. And I think that -- if I can just grab my
12 papers, you know, there's a couple of things. I mean, you do
13 have -- and we have the motion with the proposed instruction.
14 But, you know, let me just read -- you know, the question posed
15 by the superseding indictment is not whether the defendants
16 engaged -- we have a motion but I don't want to file it because
17 you have enough paper -- an off-label promotion after having
18 been told it was illegal. The question in the indictment is
19 can the government prove beyond a reasonable doubt the elements
01:03 20 of the charged offenses. And misbranding includes an intent to
21 defraud or mislead.

22 The slide -- before the slide, if you peel back One
23 there, is: "Do not promote off-label. Do not mix. Do not
24 share recipes. Do not recommend the use of Calstrux and OP-1
25 Implant. To not give directions for mixing Calstrux and OP-1

1 Implant. No off-label promotion or off-label activities will
2 be tolerated."

3 Turn the page. "Consequences of off-label
4 promotion" -- right there -- "criminal misbranding
5 prosecution." That's what we have here. But, your Honor, we
6 have a felony criminal off-label promotion case in Counts 7
7 through 12 against the company.

8 And so what the jury is going to go home for the
9 weekend and listen through at least the government's case
01:04 10 believing is that what they were -- what's instructed on the
11 "do-not" slide is criminal misbranding like we have charged
12 here. It is not. There is a misdemeanor -- you can charge it
13 as a misdemeanor, strict liability offense.

14 Your Honor, we wouldn't be here if that's what the
15 government had wanted to do. So they're trying to turn it up,
16 get the heavy penalties, charge a fraud misbranding case, but
17 have the jury take the law from John Houghton's slide deck.

18 And so we would like you, if you're not going to
19 strike the slide, to instruct them with respect to, you know,
01:04 20 A, the law comes from the Court. You mentioned earlier, you
21 know, that all of these offenses require proof of fraud,
22 including misbranding, which has an intent to defraud or
23 mislead element to it. Because otherwise, I just think the
24 danger of unfair prejudice to these men, Jeff, Bill, Dave, and
25 to this company, is too great.

1 THE COURT: Mr. Sternberg?

2 MR. STERNBERG: Thank you, your Honor. A couple of
3 things about the slides. First, the crimes at issue all
4 require acts and then proof of intent. The slides at
5 issue -- the conclusion slide, the one that says "do not," "do
6 not," "do not," talk about a series of acts that are being
7 communicated to the sales force not to engage in.

8 The consequences slide then talks about potential
9 consequences for those acts. They don't -- as a matter of --
01:05 10 as the defense has put in one of their briefs, as a syllogism,
11 say one follows the other. Intent will have to be proven and
12 cannot merely be proven by looking at the slide, but by what
13 other acts there were, what other evidence was there of their
14 mental state after March of 2006. The slide, though, is highly
15 relevant to what these people were told they should and
16 shouldn't do and how serious that instruction was given the
17 potential consequences that they were talking about.

18 Mr. O'Connor talks about a jury instruction to be
19 given now which the government objects to. Mr. O'Connor gave
01:06 20 the jury quite a bit of law yesterday about misbranding and
21 off-label promotion. Mr. Houghton is not going to be
22 testifying as an expert; he's going to testify about the
23 process he went there with other of his colleagues to develop
24 the slide set; the manner in which he gave it; who got it; what
25 was said; what the responses were. And then there will be

1 evidence of other trainings during the course of this trial
2 that postdated Mr. Houghton's training in 2006 and 2007. And
3 there will be other evidence that either will or will not prove
4 the intent of the defendants.

5 But this is a key milestone in this case and a key
6 piece of evidence that should come in, and should come in
7 without any jury instruction at this time that would highlight
8 it over any of the other pieces of evidence that are going to
9 come in during the course of the trial.

01:07 10 MR. O'CONNOR: Your Honor, there will be no other
11 evidence -- no other evidence -- in this case like this slide.
12 None. And so we -- we just say -- and, you know, Mr. Sternberg
13 said in the filing on November 9th, "We're not trying to
14 bootstrap a misdemeanor misbranding charge into a felony
15 conspiracy charge."

16 Well, let's tell -- have the Court tell the jury what
17 the law is. This is a compliance -- you know, this is
18 compliance training. This is the most significant, by far --
19 if they've got a little other compliance training in the case,
01:07 20 it's nothing like March 1, 2006. Ms. Winkler -- they
21 featured -- I've got eight quotes from her. It's from this in
22 her opening. And she is trying to set the bar at: If you do
23 the things on the "do-not" slide, you are guilty of criminal
24 misbranding, which is charged here.

25 But we have felony criminal misbranding, intent to

1 defraud. They said it from the beginning: This is a fraud
2 case. That's why it's a felony. It is not a strict liability
3 misdemeanor case. They are trying to bootstrap a misdemeanor
4 case into a felony conviction. And that's not fair. And
5 that's what 403 is about.

6 So I think, your Honor, if you're going to allow
7 them -- and I understand why you would -- to use the slide --
8 because the government makes good points about, you know, the
9 evidence of intent and all of that is important, but I just
01:08 10 don't want them to be confused about what the standard is, what
11 the question is that they're supposed to be focused on.

12 If I were them, even as a lawyer I'd think that, well,
13 you're putting in this. It sounds legal to me. "Criminal
14 misbranding prosecution." "Serious offense." "Illegal."
15 "Criminal prosecution and criminal fines." That's legal talk.
16 And it's fine if they want to say, "Listen, people went out and
17 gave out mixing instructions without surgeon questions or
18 requests for information after this." I'm willing to live with
19 that and we can deal with it. But I think we can't deal with
01:09 20 the jury having the understanding, as they listen to six weeks
21 of evidence, that, you know, this is the -- the question is
22 just affirmative -- you know, without any discussion by these
23 men, sales reps for whom the company's responsible about the
24 mixture. Because that's what they're going to think the case
25 is about.

1 And it's a long time -- we have to sit there -- and
2 even when we get to our case -- I mean, unless we put on a
3 legal expert, which we don't want to do, obviously. You know,
4 I don't know how you -- how you undo the misimpression, if
5 that's what they have, if I'm right about that, about, you
6 know, what the government's shooting at.

7 MR. ULLMANN: Very briefly, your Honor. On behalf of
8 the three individual defendants, we don't think the slide is
9 fair, we don't buy the government's arguments at all, and we do
01:10 10 think the issue is broader than just confusion about
11 misdemeanor misbranding versus felony misbranding. We think
12 that clearly the government wants the jury to conclude from
13 that slide that these three individuals and the company are
14 guilty of all the charged offenses.

15 THE COURT: All right. There's no question that each
16 of the counts requires proof of fraud and, therefore, intent to
17 defraud. It seems to me that the three openings by the defense
18 yesterday emphasized that point. I think the jury probably
19 absorbed it.

01:10 20 I'm not going to instruct at this time, principally
21 because I am not going to instruct before I've heard the
22 evidence, on a prediction of what the evidence will be. And
23 not only does it go to whether there should be an instruction
24 but how it should be framed.

25 So there will be time to emphasize and, I think, make

1 clear to the jurors what the issues are and how they're to
2 resolve them, and we'll be aware of that, but the distinction
3 between proving a simple misbranding, or an off-label use
4 promotion or something like that, and the crimes charged is a
5 distinction that we will observe, but at the appropriate time.

6 MR. STERNBERG: Your Honor, there's one other issue
7 with respect to --

8 MR. O'CONNOR: Thank you, your Honor.

9 THE COURT: So I will neither exclude the slide nor
01:11 10 instruct at this point.

11 MR. STERNBERG: Your Honor, there's one other issue
12 with respect to immunity, or maybe a broader immunity issue we
13 wanted to discuss with the Court at sidebar, if we could.

14 THE COURT: Do we need to do it now?

15 MR. STERNBERG: It is relevant to the first witnesses
16 witness.

17 THE COURT: Okay.

18 (Discussion at sidebar and out of the hearing of the
19 jury:)

01:12 20 MR. STERNBERG: The form of immunity order that we're
21 using says if the witness refuses to testify, then immunity
22 flows from that. Given the regime we're operating under,
23 counsel for the witnesses have been asking how do we know the
24 immunity is operative. In keeping with the Court wanting
25 to -- as long as the defense is not going to cross-examine

1 about the immunities, our suggestion is that the Court can say
2 on the record that for all the orders that have been signed by
3 the Court, the immunity is active and, therefore, for the
4 witnesses the defense is not going to cross-examine, we can
5 communicate that to those witnesses.

6 MR. O'CONNOR: That's a good way to handle it.

7 MR. GURNEY: That's fine.

8 THE COURT: Rather than have to put them on and have
9 them refuse and so on and so forth? Well, if that's the
01:13 10 agreement of the parties, then --

11 MR. O'CONNOR: I think it's a good suggestion and I
12 appreciate it.

13 THE COURT: -- I guess what happens is I can accept
14 the representation that all of the witnesses have stated, and
15 all counsel agree that they have done so, that they will not
16 testify without immunity.

17 MR. O'CONNOR: Yeah. I think that's fine.

18 THE COURT: So we can take that as a fact.

19 MR. STERNBERG: Okay. And I'll communicate that.

01:13 20 The other issue --

21 THE COURT: Now, Houghton is the first witness? So he
22 has an immunity order?

23 MR. O'CONNOR: Uh-huh.

24 THE COURT: Are you going to --

25 MR. O'CONNOR: Thank you, your Honor. We're

1 committing not to impeach him.

2 MR. STERNBERG: On that point, because counsel for the
3 witnesses are asking us the night before, the day before, can
4 we ask for 24-hour notice on that?

5 MR. O'CONNOR: Absolutely. Absolutely. That's fair.

6 THE COURT: Is he going to be the rest of the day
7 after we finish the opening? Predictably, anyway, a couple of
8 hours? So it will be 10:30 or something?

9 MR. LIBBY: Yes.

01:14 10 MR. O'CONNOR: I'm not sure on that. I
11 don't -- I'm --

12 THE COURT: The only reason I ask, is there any issue
13 with the next witness?

14 MR. O'CONNOR: Oh, yeah.

15 MR. LEVY: We won't be impeaching.

16 THE COURT: Okay.

17 (In open court:)

18 THE COURT: Okay.

19 MR. NOONAN: Your Honor, the government's logistical
01:15 20 issues can probably wait. Let's crack on.

21 THE COURT: All right. So we're ready for the jurors.
22 Now, one minor thing --

23 You can start doing this and I can talk.

24 -- I am going to permit them to take notes. I didn't
25 address it yesterday because I thought I'd do it when we were

1 handing out the pads. So I'll pause to tell them that they can
2 take notes.

3 MR. NOONAN: Your Honor, does the Court allow them to
4 take notes during the closings as well?

5 THE COURT: No. No, just the evidence.

6 (Pause.)

7 THE COURT: We won't do it now because there's still
8 an opening to be done, but after Mr. Libby's opening we'll do
9 it.

01:16 10 Are you using the chart? Yeah. The monitors at all?

11 MR. LIBBY: No, your Honor.

12 (Pause.)

13 THE CLERK: All rise for the jury.

14 (The jury enters the courtroom at 9:54 a.m.)

15 THE CLERK: Please be seated.

16 THE COURT: Good morning, jurors.

17 THE JURORS: Good morning.

18 THE COURT: As I predicted, there were a couple of
19 issues the lawyers and I had to deal with, and we've resolved
01:17 20 them now and we're ready to proceed. So we have one more
21 opening statement and then we'll commence the evidence. So
22 Mr. Libby on behalf of Mr. Whitaker.

23 MR. LIBBY: May it please the Court, counsel, and may
24 it please you, ladies and gentlemen of the jury. Once again,
25 my name's Frank Libby, and together with my colleague, Althea

1 Porter, we're proud to represent Jeff Whitaker.

2 You've been very patient yesterday and again this
3 morning. You've heard a great deal already. A lot of
4 material. Several hours of presentation by some very
5 experienced counsel on a matter that's very likely unfamiliar
6 to you. And I was planning on asking you to hang in there just
7 a little bit longer, telling you that it was just one more
8 opening statement, but that wouldn't do justice to this moment
9 because it doesn't come near capturing what's really unfolding
01:18 10 before you right now.

11 I'm standing before you on behalf of a good and decent
12 man. His entire life he cared deeply about how he carries
13 himself, how he behaves, how others view him. He cares deeply
14 about his family, his friends, his colleagues at Stryker and in
15 the relatively small surgical community, surgeons and the like,
16 what they think about, what they say about him. Simply put:
17 Jeff Whitaker is eager to be both exonerated in this criminal
18 matter and to clear his good name, the name that he has built
19 up his entire life.

01:19 20 He wants to do that very much in the course of this
21 proceeding with you, and he wants to get this
22 process -- everybody wants to get this process underway, with
23 you all as the judges of the facts. You and you alone find the
24 facts in this case. And that begins with testimony which
25 commences virtually immediately after I'm done. But I make no

1 apology for taking this time with you.

2 So Jeff Whitaker: He's a family man. Married Linda
3 about 20 years ago. Two young children: Jacob and Hannah.
4 She's home taking care of them. Jeff grew up and attended high
5 school in Maryland and South Carolina, and graduated college in
6 1985. He bounced around at a couple of entry-level positions
7 after graduating college and then had the great fortune to join
8 the medical-device industry.

9 His first job in the medical-device field had to do
01:20 10 with legs, anti-coagulation devices and the like. Prevents
11 deep vein thrombosis. So why is that important to mention?
12 Because it was his first opportunity to deal with a very select
13 customer base: doctors, surgeons. He called on them. He
14 found it was an exciting new world. These are busy people with
15 serious work. And he came to appreciate what they're able to
16 do and how they go about their work.

17 He came to know and respect individual surgeons not in
18 the role of a patient like you or I would typically, but to
19 present himself as a potential asset, a resource to that
01:21 20 surgeon, to that doctor. And after some time Jeff concluded,
21 Do you know what? This is pretty good. This is a great way to
22 make a living. This is meaningful and this is what I want to
23 do.

24 So after some time he moved on from legs to knees. He
25 worked for a company that sold surgical instruments for

1 arthroscopic surgery and the like, provided stability to the
2 knees. And then moved up to the shoulders. Started with legs,
3 knees, now shoulders, rotator-cuff surgery-type instruments,
4 and so on, suture anchors, to stabilize the shoulder.

5 In 2002 Jeff had the great fortune to join Stryker
6 Biotech. And what an opportunity. He moves from
7 instrumentation-type devices to the cutting-edge world of
8 biologics. His initial experience was with OP-1 Implant.
9 Mr. O'Connor told you a little bit of history about OP-1
01:22 10 Implant with the long-bone nonunion product. A year or so
11 later Implant was joined on the market by OP-1 Putty. You
12 heard a great deal about that already. That's the bone
13 morphogenetic protein.

14 Now, here some of the most demanding customers on the
15 planet, neurosurgeons, orthopedic surgeons, he's dealing with
16 them on a routine basis. It's a demanding task, but if you
17 know your stuff and you're good at what you do and you know
18 people -- and sales is all about people. It's all about trust
19 and confidence -- you can build solid working and professional
01:22 20 relationships and you have a shot at growing a loyal customer
21 base, customers who will not only come to know you and respect
22 you and trust you, but give your name to other surgeons.
23 That's how you make a good living and you carve out a career
24 for yourself, a future for yourself and your family.

25 Now, you heard from Ms. Winkler, Jeff was a regional

1 sales manager for Stryker. He was proud to be a regional sales
2 manager for Stryker. In '05 he became the southeast sales
3 manager, and then in late '07 he became the eastern region
4 sales manager. Now, it's not a manager in the executive sense
5 of the word. He worked out of his home, North Carolina. He
6 doesn't hire or fire. He doesn't make salary decisions or
7 design training in any way. That's all handled elsewhere in
8 the company. But he's an experienced sales motivator, a
9 communicator and a facilitator for the ten or so reps that he
01:23 10 covers in his territory.

11 And that includes traveling throughout his region,
12 supporting his reps, looking after their well-being, and going
13 on things you'll hear called ride-alongs. A territory
14 manager -- or, rather, a sales manager, a regional manager,
15 will go and see a rep and go on some rides, pay visits to
16 surgeons in their offices, see how his reps are handling
17 themselves in the field.

18 So from years of experience in the surgeons' offices,
19 in and around hospitals and surgical clinics, Jeff helped his
01:24 20 sales reps learn the ropes, learn -- he learned the ropes, and
21 he would teach his reps how best to prepare to help the surgeon
22 and actually be helpful to that surgeon. You'll see and learn
23 how his own people uniformly thought very highly of him; valued
24 his energy, his willingness to step up and to help with
25 whatever they needed.

1 So let's fast-forward to the present. Jeff's day in
2 court begins right now -- right here, right now. And this is
3 my opportunity on behalf of Jeff to tell you what I believe
4 this case is fundamentally all about. Now, I'm not going to
5 intentionally go into plowing the ground that these lawyers did
6 yesterday. I'm not going to try to do that. I'm going to try
7 to avoid that. There may be some overlap, but I'll see if I
8 can avoid it. Rather, I'm going to suggest to you two, and
9 only two, guideposts to keep in mind as you listen to the
01:25 10 testimony, you see the evidence, you hear the people from the
11 witness stand.

12 And those two points -- each of those two points have
13 to do with one thing, and that's being free to do your job.
14 Being free to do your job. One -- Mr. O'Connor briefly
15 mentioned this yesterday and I want to underscore it -- the FDA
16 may not interfere in the practice of medicine. The FDA may not
17 interfere in the practice of medicine. That means doctors,
18 surgeons, are free to call the shots -- all of them, because
19 it's their obligation to call the shots -- regarding the care
01:26 20 and treatment of their respective patients.

21 The FDA's role as a regulator is, of course,
22 important, but at the end of the day -- at the end of the
23 day -- it's the surgeon's decision. And the surgeon's decision
24 regarding his patient trumps the FDA, something you didn't hear
25 from Ms. Winkler yesterday. That's one.

1 Two: When a surgeon asks for help or poses a question
2 to a manufacturer's rep, a sales rep, regarding the care or
3 treatment of that surgeon's patient, the rep -- such as Jeff is
4 a rep, now he's a regional manager -- they're completely free
5 to respond -- completely free to respond -- to that request for
6 help, or that question. Another item not included in
7 Ms. Winkler's comments.

8 Now, doctors know this. They know they're free to
9 practice medicine, and so do those in the medical-device
01:27 10 community, including Jeff. He knows it too. You'll see from
11 the evidence that Jeff acted in good faith, that whatever the
12 circumstances were, he believed he should be prepared to
13 respond and that it was perfectly permissible to respond to
14 that request for help.

15 Now, why do I single out these two points up-front
16 first? Because the government has charged Jeffrey Whitaker
17 with fraud; that is, lying and cheating surgeons. Lying and
18 cheating surgeons. Make no mistake. That's the
19 charges -- those are the charges in this case. And to convict,
01:27 20 they have to prove to you, ladies and gentlemen, among other
21 things, and beyond a reasonable doubt, that Jeff -- this man,
22 Jeffrey Whitaker, had criminal intent. And not just any kind
23 of intent -- any kind of criminal intent -- specific intent.
24 Specifically intended to defraud a surgeon, to lie, to cheat a
25 surgeon. And here's the home-run point: Good faith is

1 completely inconsistent with an intent to defraud. Completely
2 inconsistent with an intent to defraud.

3 You will conclude that after all is said and done and
4 all the evidence is in in this case, contrary to believing that
5 any of his actions were criminal, Jeff had every good reason to
6 believe and, in fact, believed genuinely that he was acting in
7 good faith. He was doing good. Helping a surgeon, in turn,
8 help that surgeon's patient.

9 So here let me be a little more visual and offer a
01:28 10 scenario where both of those things are in play.

11 If I may, your Honor?

12 THE COURT: Go ahead.

13 MR. LIBBY: It's going to be to your back, but this is
14 what we have here. Can everybody see this okay?

15 Now, these two principles I'm talking about are
16 actually at play in what you see here in this photograph. And
17 they're at play with -- everybody in this room has to be on his
18 or her own toes. And that takes place every day in every
19 operating room in this nation.

01:29 20 One way or another, virtually everything you hear and
21 see in this case is going to come down to this. All of it.
22 All the evidence in this case. Everything you need to decide
23 about the government's charges can be found right here. It's
24 personified in what you see here.

25 This is the operating suite, the operating room.

1 You're going to learn from the evidence in this case, ladies
2 and gentlemen, how the surgeon, this gentleman right here with
3 his back to you, bent over as tasked, calls all the shots in
4 the operating room to include who's in the room, what takes
5 place, at what stage, in what manner, and for what purpose.
6 Everything. The surgeon.

7 So it's a little tight quarters here and it doesn't
8 capture everybody in the room, but just so we're clear we have
9 a patient you can't see. The surgeon is bent over him. We've
01:30 10 got the scrub nurse, the surgical assistant; we've got the
11 neurology, radiology folks. Why do we have radiology? We're
12 dealing with spines, bones, constantly taking X-rays. That's
13 why we're wearing lead vests.

14 We have a circulating nurse -- not in the photograph
15 here, but every one of these procedures -- you'll learn about
16 the surgical procedure, including who's in a room, what
17 happens. A circulating nurse is not in the sterile field.
18 That's the area immediately above the incision. Nothing can go
19 in there unless it's sterile. It's called the sterile field.
01:31 20 The circulating nurse gets whatever product, boxes, opens the
21 boxes, makes sure the instruments from the back table are made
22 available to the scrub nurse and so forth. So it goes
23 circulating nurse to scrub nurse to the assistant, and
24 ultimately, the surgeon.

25 And that circulating nurse is documenting in real time

1 everything that is being used in that surgery. Everything.
2 Documenting it so there's a record, a real-time record so
3 you'll know -- and you can see. And you'll see documents in
4 this case -- what happened in that room, two- or three-hour
5 procedure. A complete record. What was used, who was there,
6 who did what, when.

7 Now, I haven't talked about this fellow right here in
8 the red vest. This might surprise you, but that's the
9 medical-device representative. Why's he there? Well, we'll
01:32 10 tell you later. You'll learn why he's there. He's there often
11 at the request, and most often at the insistence, of this man,
12 the surgeon. He's not barging in. He's expected to be there
13 under the complete direction and control of the surgeon.

14 Now, here he's using a laser pen. You'll see here,
15 you'll learn that because the rep is not in the sterile field
16 and he's not scrubbed in and he's not, in fact, involved in any
17 way physically with the surgery, he needs to point out
18 products, boxes and so forth, and talk to the circulating nurse
19 and make sure that people are getting what needs to be gotten.

01:32 20 He never opens a box or moves or touches an
21 instrument, but -- and you'll hear about this too -- he can be
22 helpful in telling the surgical team, maybe unfamiliar with the
23 vials -- and you've seen a couple of the vials of OP-1 and
24 Calstrux in this case -- how to open it. It's not easy. It's
25 got serrated edges; it's got rubber stoppers. They want to

1 make sure that people open this properly when it's time. And
2 this gentleman here says when it's time.

3 Now, he doesn't simply show up. These are calendared.
4 These procedures -- as you might imagine, it's a fairly
5 complex, significant procedure for everybody involved. There's
6 a game plan. It's scheduled. Need to know who's on the team,
7 who's going to be there, how much product is necessary. It's
8 all played out ahead of time. It's too late once this
9 procedure gets underway to try to figure out how much product
01:33 10 is necessary for whatever the procedure is. So the bottom-line
11 dynamic, you'll find -- you'll find in the course of this
12 trial -- is that this person's purpose is to do all he or she
13 can to help this person do all he or she can to help the
14 patient. That's it. That's what this case is all about.

15 Now, the patient -- a word about the patient you don't
16 see here in this photo. At this stage in this kind of
17 surgery -- leading up to the surgery, rather, there's just only
18 one word for this patient's life, and that's miserable.
19 Whoever that person is has been dealing with spinal instability
01:34 20 for years. After years of pain management and physical therapy
21 and so forth and so on, this person has been effectively
22 deprived of all daily functions of life and enjoyment of life.
23 They consider themselves out of the mainstream of family life
24 and business life. They can't move. They can't bend over.
25 They can't lift. They can't sleep. They can't walk. They're

1 at the end of their rope.

2 Now, 20 years or so ago all that was available to help
3 folks like that -- some folks like that -- was the procedure
4 that Mr. O'Connor laid out for you yesterday, and that's the
5 iliac crest graft surgery. Brutally painful. Even with
6 anesthesia, brutally painful. Patients will tell you they
7 don't want to go through that. They could feel the hollow
8 piece from their hip. It's where they go in, they crack open
9 the hip with a hammer and chisel and pull out that soft bone.
01:35 10 They need the person's own bone to try to make a fusion in the
11 spine, basically.

12 But for some they can't even -- years ago they
13 couldn't even submit to that procedure. They were just flat
14 out of luck. They weren't good candidates for it. And, again,
15 Mr. O'Connor mentioned briefly some of those folks weren't good
16 candidates because they didn't -- they had poor bone quality,
17 if they had any bone available at all for that type of
18 procedure, iliac crest graft. These are people who were
19 elderly, smokers, diabetic, osteoporosis, had a prior failed
01:36 20 surgery. There wasn't any bone left to go back and get. So
21 their misery continued, no options.

22 Then along came bone morphogenic protein, a brand-new
23 day for spine surgery. A brand-new day for spine surgeons.
24 And that's why, ladies and gentlemen, this man joined Stryker.
25 He saw it for what it was: a great development. Patients were

1 no longer shut out of the operating room by poor bone. It's a
2 huge leap forward.

3 You heard Mr. O'Connor talk about Stryker's research
4 and development story. This is the kind of -- this is the kind
5 of product, this OP-1 -- it's like a radio signal. Very strong
6 radio signal. A hundred, even a thousand times stronger than
7 your own bone. Tells the body: Grow bone. Fill in, give me
8 stability in my spine. Surgeons don't have to go and tell
9 their patient, You've got to undergo this crest graft, this
01:36 10 hip -- we're going to crack open your hip. He doesn't have to
11 say that anymore. So most of all, with the advent of BMPs,
12 surgeons can say yes to these people that were previously out
13 of luck.

14 So in the course of this trial you're going to learn
15 surgeons obviously wanted to avoid exposing their patients to
16 this unnecessary pain, and not for nothing, additional surgical
17 procedure concerning the risk of anesthesia and so on and so
18 forth. Two procedures. They understood the benefit of BMPs.

19 A little bit of relevant history. Just a little. The
01:37 20 first on the market was not OP-1. It was a thing called
21 InFuse -- a product called InFuse -- from Medtronic. First on
22 the market. The surgeons became familiar with InFuse, and then
23 they began combining InFuse with other materials to give it
24 volume and handling, okay?

25 And the scaffolding. The scaffolding -- you heard the

1 term "scaffolding" already. It's something to grow on. When
2 the active ingredient sends that signal to grow bone, it's got
3 to grow on something, to provide scaffolding. So doctors were
4 already mixing before OP-1 came on the market. And all that
5 was widely known in the spine surgery community and the
6 medical-device community, known to Jeff. OP-1 later came on
7 the market as an approved product. Now that's available to
8 surgeons as well. And sometime later Stryker launched
9 Calstrux, the TCP product, that tricalcium phosphate which
01:38 10 occurs in things such as you see in this Gerber baby food.

11 You'll also hear a constant reframe, and the evidence
12 in this case, and that is this: Surgeons ask each other and
13 reps all the time about mixing, combining products. All the
14 time. Mixing was the standard of care throughout this whole
15 time. Surgeons believe that combining an active ingredient and
16 inert materials such as TCP was beneficial. It was the best of
17 both worlds. It provided the bone growth signal and the
18 scaffolding on which to grow the bone. You're going to learn
19 again that all of that was widely known in the medical-device
01:39 20 community, to folks including Jeff.

21 Surgeons, their surgical teams and the sales reps
22 providing the latest, greatest advancement all believed -- all
23 of them believed -- they were playing a genuine role towards
24 greater prospects for successful surgical procedures. And
25 you'll see and hear in this case, in this courtroom, the very

1 same thing Jeff and his colleagues saw and heard: that OP-1
2 provided a second chance, wonderful opportunities for a vastly
3 improved life. Get these people back to their near-normal
4 daily function. No more pain. I can sleep. I can walk. I
5 can lift. And in some cases with trauma patients, I don't have
6 to lose a limb. I don't have to lose a limb.

7 These are wonderful opportunities for surgeons. These
8 are folks -- the gentleman here an example among them --
9 they're wired to move. They're active people. They want to
01:40 10 help. They want to achieve things. They want to accomplish.
11 They want to use everything that's available to them to
12 maximize their ability to get a good result for their patients.

13 So why's this important to go into this with you here?
14 Well, in addition to the wonderful results themselves, far from
15 any criminal intent of any kind, these results add to Jeff's
16 store of understanding, knowledge and appreciation of the
17 wonders that OP-1 brings to patients. Jeff and his colleagues
18 are personally and professionally motivated by these success
19 stories. They give them pride in what they do, in their work,
01:40 20 and why they can offer surgeons a way out.

21 Now, surgeons. Very briefly. You're going to see and
22 hear from several of them. These are the folks who deal with
23 the spine. Orthopedic surgeons and neurosurgeons, they both
24 cover the human spine. Needless to say, they're highly
25 educated, skilled and trained. I would consider them the

1 fighter pilots of the surgical community, the very best of the
2 best. They're busy people. You'll hear about their
3 time -- their tight time clock and time management day in and
4 day out. They have special surgery days. They do rounds.
5 They have time set aside for new patients. They're not very
6 casual in their workplace, as you might imagine. And they
7 can't and don't tolerate folks on their team who don't show up,
8 don't perform and don't come prepared for business and aren't
9 prepared when the surgeon poses a question or asks for help.

01:41 10 Sales reps, the entire medical-device community, know
11 this, including Jeff. This is a relatively small tight-knit
12 surgical community, you'll learn from the witnesses on the
13 witness stand. They stay up on the latest advancements and
14 techniques in this kind of surgery. They talk to each other
15 all the time. What better source than your colleagues, who are
16 also your competitors for the surgical business? They go to
17 the same lectures, they read the same literature, they attend
18 the same conferences, and they're all on the internet. They
19 want to be the best at what they do. And that's where it comes
01:42 20 from, that information, all those sources.

21 Sales reps know this too. And you're going to -- in
22 the operating room -- in the operating room -- this man's word
23 is law. He's got the first word, he's got the last word, and
24 every word in between. That man. You're going to hear from
25 some of them yourself. You'll see them on the witness stand.

1 You can size them up all yourself. And you're going to see --
2 what you're going to see and hear is that they call the shots.
3 All of them. The who, what, when, where, how. All of it. And
4 why? Ultimately, because they're accountable. They're
5 responsible for that patient and the patient's family. They're
6 the ones who walk out of the operating room and talk to the
7 family. They're accountable at the end of the day.

8 So for that reason, among others -- and as I pointed
9 out in the beginning of my comments but it bears repeating
01:43 10 here -- you're going to learn that a surgeon is free to
11 practice medicine without interference from the FDA. He's
12 accountable. He's free to practice medicine. Surgeons will
13 tell you that while there's a lot of science involved, once
14 that surgical procedure begins, the incision is made, that's
15 when the surgeon sees the landscape, actually sees what he's
16 dealing with in that spine. And he sees where he's got room to
17 act, what it is that he needs to do now that he couldn't see
18 before.

19 And he'll tell you there's far more art than science
01:43 20 involved in this. Now I've got a decision to make. How do I
21 help this patient right here, right now? Each patient is
22 different. No surprise there. Each procedure is
23 correspondingly different.

24 So you're going to hear a lot about things such as the
25 space to be filled in the gutters. You'll hear about gutters,

1 the space to be filled. The volume that I need -- the
2 consistency. The handling -- the surgeon needs to deal with
3 this now in the course of the procedure. The surgeon then
4 believes in those. "I have to have everything available to me,
5 all the tools and resources, everything. My training -- I
6 bring to bear my training, my education, my experience, my
7 expertise, and my independent exercise of medical judgment."

8 Now, the surgeon, as with any doctor, is completely
9 free to make his or her own decisions, to elect, to prescribe
01:44 10 or use for any purpose any drug or device lawfully on the
11 market. He can reach anything that's lawfully on the market in
12 the exercise of his independent medical judgment. That
13 includes devices such as OP-1, Calstrux, or any other inert
14 substrate, as we call it. That's the mixing material. And any
15 combination of the two. Any combination of the two.
16 Completely free to reach and use those things as he or she sees
17 fit in the course of the surgical procedure.

18 Now, I expect that you'll see instances in this case,
19 primarily emails, of Jeff's discussing with his colleagues
01:45 20 various ways that spine surgeons in their discretion might --
21 given the history of mixing and combining generally, how they
22 might consider and ultimately decide, the doctors -- rather,
23 the surgeon calling the shots -- they might decide to combine
24 these products. Their call. That's their shot.

25 And in doing so, you'll see that Jeff, as a

1 knowledgeable device representative and regional sales manager,
2 is genuinely trying to be helpful both to his sales reps and,
3 in turn, to the surgeon in every case. That's all there is to
4 this case, ladies and gentlemen. He's not hiding a thing.
5 It's completely out in the open. He's acting completely in
6 good faith rather than criminal, as the government charges
7 here.

8 Now, you're going to learn that the medical-device
9 community, including Jeff, all knew and understood these
01:46 10 critical points: One, again, that the FDA may not interfere
11 with a physician's judgment in the practice of medicine; and,
12 two, that that judgment encompasses everything about the care
13 and treatment of the patient including the use of medical
14 devices, again, such as OP-1 and bone void fillers such as
15 Calstrux, and that surgeon's judgment includes such decisions
16 as to whether to use any device on-label or off-label.

17 Now, you heard a great deal from counsel yesterday
18 about those terms, on-label, off-label. There's nothing bad
19 about off-label. There's nothing bad at all. You'll hear that
01:47 20 too from the physician. Oftentimes off-label is the standard
21 of care. It's way ahead of the FDA. And I told you I wouldn't
22 plow old ground, and I'm going to do my best to keep that
23 promise and move this along. But please bear this in mind when
24 you listen to the evidence -- please bear these three points in
25 mind: One, the FDA rules and regulations, the administrative

1 rules and regulations, can be and often are complex, vague and
2 inconsistently conveyed and interpreted. And that's when
3 they're conveyed at all, which will be an issue in this case.
4 I'm not going to get into the details of that last point, when
5 they're conveyed at all, but pay particular attention -- I
6 would ask you to pay particular attention to the evidence
7 showing the disconnect between what John Houghton, the
8 government's first witness, believes he achieved during his
9 conference call with the sales force -- you're going to hear
01:48 10 about that very shortly -- and what the members of the sales
11 force actually took away from that call. You'll find two very
12 different things, ladies and gentlemen. That's one: the FDA
13 rules and regs. Complex, vague and inconsistently conveyed.

14 Two: Jeff genuinely believed and had every good-faith
15 reason to believe that he and his reps not only could but
16 should be prepared to respond to a surgeon's question or
17 request for help and to, in fact, respond to that question or
18 request. And that includes -- that encompasses any surgeon's
19 question regarding mixing or combining two or more devices, if
01:48 20 you will, such as OP-1 and Calstrux. He had every good-faith
21 reason to believe that he could respond to a surgeon's request
22 when it came to that, combining products, because the doctor is
23 completely free to do that.

24 Third and last: This is not a regulatory case. This
25 has nothing -- this is not a diminished regulatory case. There

1 are no administrative or regulatory charges against Jeff or any
2 of these men or the company in this case. The Court's going to
3 give you the law at the end of this case, but for now, please
4 bear in mind this is a criminal case. There is far more at
5 stake here.

6 And for this reason, the question for you as jurors
7 will not be whether Jeff, or any particular sales rep or
8 defendant, actually stayed inside or stumbled or strayed
9 outside the white lines of any agency regs or standards or
01:49 10 policies regarding promotion or anything having to do with the
11 interaction with surgeons. That's not this case. It's not
12 about staying within the white lines or stumbling or straying
13 outside the lines.

14 Even if Jeff or a sales rep might later be found or
15 thought to have run afoul of those rules or regs, the actions
16 at issue, and you're going to hear about them in this case,
17 were completely motivated by a genuine good-faith impulse to be
18 of help, to actually help. And that's the polar opposite of
19 criminal.

01:50 20 Now, very briefly, Ms. Winkler made a few comments on
21 this conspiracy -- this conspiracy to defraud the FDA and to
22 defraud surgeons. And a couple of points very quickly. First,
23 to defraud the FDA. There's not going to be any evidence,
24 ladies and gentlemen, of Jeff targeting, entering into any kind
25 of unlawful agreement to target or otherwise conspiring to

1 defraud the FDA. He had no dealings with the FDA. There's no
2 evidence of any dealings with the FDA. You will not see it.
3 He couldn't find the FDA with a map. So that's not an issue in
4 this case, respectfully.

5 Defraud surgeons. Ms. Winkler made a couple of points
6 yesterday about Jeff and defrauding surgeons. And it takes two
7 forms. The first is some comment about how surgeons are handed
8 a ball of Calstrux, and Jeff allegedly trained a rep to say
9 something like, "This is what OP-1 is going to feel like."

01:51 10 That's in the course of a ride-along, where he goes into the
11 various territories and he rides along with the sales rep.

12 Well, you'll learn that, actually, that's true.
13 Surgeons will tell you, yes, that's what it does feel like.
14 That's what it does feel like when it's combined. Again,
15 they're looking for handling characteristics, volume. You'll
16 hear these words: consistency, malleability. Will it work
17 when I'm in a surgical operating room? You'll recall that
18 mixing is a given; it's a standard of care at the time all of
19 this is happening. Even before OP-1 came on the market.

01:52 20 Now, a surgeon's interested in the BMP, the bone
21 morphogenic protein. And here that's the active ingredient.
22 In our case it's the OP-1. The surgeon's interested in the
23 bone-growth qualities and properties of OP-1. But every
24 surgeon that you're going to hear from, I expect, both
25 government and defense, is going to tell you the surgeon is

1 seriously interested in, again, the opportunity for
2 scaffolding, for volume, the handling characteristics, and that
3 comes only in a combined form, not just the active ingredient
4 alone. No surgeon, ladies and gentlemen, in this case -- the
5 evidence in this case -- sees this ball and thinks it's all
6 OP-1.

7 Now, second, Ms. Winkler read to you yesterday an
8 email, a message by Jeff in response to a question from
9 headquarters about what kind of questions can you expect,
01:53 10 anticipate in connection with a proposed letter going out.
11 "What do you think the sales rep's going to say, what do you
12 think the surgeon's going to say when they see this letter?"
13 And in response, as she read, pointed out, identified,
14 highlighted, one part of that email said, "Some doctors are
15 handed the product prior to implantation and think it's all
16 OP-1." Think it's all OP-1. The government wants to suggest
17 to you that this is evidence of Jeff's knowledge of a
18 successfully orchestrated fraud. Great. We got the doctors to
19 think it's all OP-1.

01:53 20 Nothing could be further from the truth. First,
21 Jeff's a sales guy. He's actually being frank and candid with
22 the people back at headquarters. You send this letter out,
23 here's my views. Here's the things you're going to hear from
24 the reps and from the surgeons. That's one. Not terribly
25 artful, but he's been asked his opinion on the potential

1 downsides of this controversial letter and he gives his views.
2 He's completely straightforward to the folks back at
3 headquarters.

4 Now, Jeff, as all medical-device reps, knows that all
5 surgeons mix, but they aren't focused on the particulars of the
6 scaffolding material; that is, the inert part. There's several
7 dozens of those in the market. And you're going to hear
8 about -- you'll hear and learn the identities of those on the
9 market. And, in fact, Ms. Winkler told you yesterday Calstrux
01:54 10 is nothing but a bone void filler. It's like spackle. No
11 argument here. You won't get any argument from the surgeons
12 who used it either. They'll tell you as much in this
13 courtroom. It's the same substance that's found in this baby
14 food.

15 Jeff knows this and that's what he's saying in his
16 email. He knows this, the doctors are focusing in on the
17 active ingredient. He knows it because the sales reps and the
18 surgeons game plan every surgery. They discuss and identify
19 the products to be used. And when the patient is ready for
01:55 20 implantation of the combined OP-1 and Calstrux, the combination
21 is no surprise to anybody in the room. No surprise. It's been
22 played out, planned well beforehand. So it's completely
23 understandable, reasonable, predictable to believe that
24 surgeons all think of it and call for it by name. "I'm ready
25 for the OP-1." "I'm ready for the OP-1." That's the main

1 player here. That's not proof of any conspiracy.

2 So what other basis can I say in response to this,
3 they think it's all OP-1? Well, even aside from on its face,
4 it's a statement of observation; it's a remark about how
5 doctors behave and view things, about the busy lives and the
6 shorthand way that surgeons refer to the active ingredient
7 here. It's not a statement of intent. We want the doctors to
8 think it's all OP-1. He's not saying that at all. That's one.

9 Two: The internal contributions -- you'll see it in
01:56 10 the email -- it's two-faced. It's completely contradictory.
11 The government's theory here. We got a two-pronged conspiracy.
12 The first is: We're going to defraud doctors by handing them
13 something immediately before surgery and tell them it's all
14 OP-1. That's the first group. The second is: We're going to
15 defraud them by sending them mixing instructions where there
16 are two things involved. So one is: You hand them one thing,
17 they'll think it's just one product; the other part of the
18 conspiracy is we're going to defraud them by showing them how
19 to mix.

01:56 20 Well, that's a pretty tall order, ladies and
21 gentlemen, for a conspiracy. It calls for some pretty tightly
22 coordinated action between and among the coconspirators, it
23 seems to me. So you'd better have a color-coded wall chart,
24 make sure that you get your surgeons in the right group. We'll
25 have a red group. These are the surgeons with it's all OP-1.

1 And then we'll have a blue group, make sure we see that these
2 surgeons are all in the mixing instruction part of the fraud.
3 We want to make sure we don't blow our cover by putting
4 Dr. Jones, who is at all OP-1, in the part of the mixing
5 instruction part of the fraud. We don't want to do that; it
6 will blow our cover.

7 Even aside from those points, there's the fundamental
8 reality of this. It's open. It's obvious. It's completely
9 transparent. Understand what the government's claiming here.

01:57 10 This gentleman's coming in here and he wants to defraud the
11 surgeon in the course of this procedure. Well, look at all the
12 witnesses. They're all on top of each other here, one; two,
13 and I mentioned the pre-game plan. We've gone over this
14 beforehand. There is nothing surprising happening here at all.
15 It's all according to plan; and, three, the accompanying
16 documentation would choke a horse.

17 Among them you've got the informed consent, you've got
18 booking forms, you've got circulating nurse notes, you've got
19 operative notes, you've got delivered goods receipts.

01:58 20 Ms. Winkler talked about it yesterday, the little stickers you
21 pull off of the boxes from the products you actually use?
22 Well, you're going to learn they go on the invoices and they
23 get faxed back to the company. That shows what product was
24 used in the course of the surgery. That's how the company gets
25 paid. The company wants to get paid. The hospital wants to

1 know and the doctor wants to know for records what was used in
2 that room. That's a strange way to carry out a conspiracy, it
3 seems to me, to have all that documentation showing in real
4 time who's doing what, using what, in what fashion, completely
5 transparently. You're going to learn that all that
6 documentation -- all of it -- is standard in the surgical
7 community, and that, ladies and gentlemen, is all widely known
8 to the members of the medical-device community, including Jeff.

9 So bottom line, with all that in mind, the
01:59 10 government's pitch is this: This sales rep is going to try to
11 wind up and blow a curveball past this gentleman, try to pass
12 off two products as one in this room. He's going to put his
13 career, his future, his family's future, his livelihood,
14 everything on the line. He's going to pull off a federal
15 felony within one of the most orchestrated, tightly controlled
16 environments, second only maybe to Houston Control, in the
17 world. And he thinks he could get past these highly skilled
18 medical professionals with all that documentation, and he
19 thinks he can get away with it time and again.

02:00 20 For this theory to fly, the government has to be
21 suggesting -- and it has to prove to you, respectfully, ladies
22 and gentlemen -- that the circulating nurse, the scrub nurse,
23 the surgical assistant, the radiology tech, everybody is in on
24 this. Everybody is in on this except the surgeon, the
25 so-called victim of the fraud. It doesn't fly at all. None of

1 it.

2 Sales reps: You're going to be hearing from some
3 sales reps. Basically, ladies and gentlemen, these are good
4 folks, specialized education and training, all excited, proud
5 to be working for a company known as an industry leader, and
6 working together with other medical-device professionals,
7 including folks back at headquarters known to have legal,
8 regulatory, compliance training qualifications and
9 responsibilities. They all take their job seriously. They all
02:01 10 know the serious purpose of their business. They take great
11 care to know about their benefits and believe in their products
12 and the wonderful benefits that those products provide.

13 They stay current with the bone morphogenic protein
14 literature and developments in the field. You see them, you'll
15 see them here, routinely working alongside surgeons and their
16 surgical teams. They're trusted by and responsive to the
17 surgeons who are expert in their field, whom the surgeon
18 expects and, indeed, requires to be present in the operating
19 room, to be responsive to the surgeon's real-time needs.

02:01 20 That's when we get in there, we make that incision. Now we see
21 what we're dealing with. That surgeon's need for input and
22 knowledge of the product.

23 So one last time, back to the brass tacks of the
24 government's charges. They charge fraud. That's a broad term.
25 And they use terms such as craft, trickery and deceit,

1 dishonest means. But in plain English, it's lying, it's
2 cheating and stealing. Lying, cheating and stealing. The
3 charges say that Jeff, these men, company, are frauds,
4 hucksters, charlatans. And here's the MO, basically. Spent
5 all that time, effort and energy developing this wonderful
6 product, and from the sales reps' -- regional managers'
7 perspective, learn all about of those products, how they work,
8 how the surgeon can use them to benefit a spine surgery
9 patient, but don't do that for the benefit of anyone else. Do
02:02 10 it to get yourself in the surgeon's office.

11 You fly under false colors. They think you're there
12 to help them, but you're not. You're really there to make a
13 quick buck. Do you remember Ms. Winkler's comments about it
14 was all about to put money in their pockets? All of this to
15 put money in their pockets. Gain their trust, gain their
16 confidence, get into the operating room, work the con, lie to
17 them, deceive them, pick their pockets and hustle out the door.
18 That's the government's case.

19 From what you're about to see and hear in this
02:03 20 courtroom, you will conclude that nothing about those charges
21 square with what you see in this photo or who this man is.
22 Nothing. Not for a minute. Rather, you're going to find
23 good-faith motivation at every turn, and that is good faith
24 is a belief -- and I believe the Court will instruct you at the
25 end of the case. Take your instruction from him. That is a

1 belief or opinion honestly held even if it's later shown to be
2 wrong. That's completely inconsistent with the specific intent
3 to defraud, which the government must prove beyond a reasonable
4 doubt.

5 Now, in conclusion, a surgeon has a relationship with
6 the patient. A surgeon has a relationship with the patient,
7 the sales rep has a relationship with the surgeon. Jeff wished
8 to be responsive to the surgeon. He knows what the
9 surgeon -- he understands. He's been familiar. He's been in
02:04 10 these operating rooms. He's worked with surgeons before. He
11 wants to be responsive to the surgeon and generally wished to
12 be helpful in that surgeon's efforts to find a solution to the
13 patient's condition and, most often, misery. And that, ladies
14 and gentlemen, is how you carve out a long-term career in the
15 medical-device field. And you make a good living at it, to
16 boot. Nothing wrong with making a good living.

17 Now, the Court's going to tell you that no defendant,
18 none, has any burden here. I don't have an obligation to make
19 this opening statement. I don't have to question a witness,
02:04 20 offer any evidence, cross-examine anybody, lift a finger.

21 Nothing. The government has every burden all the time in this
22 case to prove its case to you beyond a reasonable doubt. And
23 that includes the obligation of proving absence of good faith.
24 I don't have to demonstrate to you good faith; they have to
25 prove absence of good faith beyond a reasonable doubt.

1 So at the close of all the evidence, ladies and
2 gentlemen, I will have an opportunity to come back before you a
3 final time and speak with you and lay out for you the many ways
4 that I believe the government has failed in its task to prove
5 any charge against Jeff beyond a reasonable doubt. Rather, you
6 will find that he acted in genuine good faith throughout here.
7 And that's when I'll ask you formally that you clear Jeff's
8 good name and return your verdict of not guilty. Thank you for
9 your attention.

02:06 10 THE COURT: Jurors, that completes the opening
11 statements. We're now going to begin the presentation of the
12 evidence. As a strict matter you have no evidence in the case,
13 yet you've heard a lot of talk about what it will be, and we'll
14 see what will happen when the witnesses begin testifying.

15 The clerk is now going to hand out some notebooks for
16 you. We're going to permit you to take notes as you wish
17 during the course of the trial to help you eventually at the
18 end of the trial in your deliberations. We often do this in
19 trials that are going to take a little while so that you can
02:07 20 jot down some things to help your memories. And each of you
21 will have a notebook, and it will be dedicated to you and kept
22 secure -- nobody else will see it -- during the trial.

23 Now, let me just say this about note-taking: Some
24 people find it helpful and take lots of notes because it does
25 help them. Some people find it an interference with their

1 ability to pay attention to what's going on in the room and
2 would just rather jot down a few things, if any, but keep
3 focused on what's happening in the testimony and so forth.

4 It is an entirely personal thing for you to do. You
5 don't have to take notes because your neighbor is doing so, and
6 so on. So to the extent it helps you as an individual, we'll
7 allow you to do it. And if you find it's not particularly
8 helpful, you don't have to do it at all. So it's just a
9 resource to have available for you to help your deliberations,
02:07 10 okay?

11 All right, Mr. Sternberg?

12 MR. STERNBERG: Your Honor, the government calls John
13 Houghton.

14 THE COURT: May I ask, Mr. Sternberg, are you going to
15 be using the electronic equipment?

16 MR. STERNBERG: I'm going to use the ELMO this
17 morning.

18 THE COURT: The jurors in the back row should get your
19 monitors ready because there will be some evidence displayed.

02:09 20 THE CLERK: Sir, do you want to step up to the box,
21 please?

22 JOHN CLIFFORD HOUGHTON, duly sworn

23 THE CLERK: Have a seat, please. State your name and
24 spell your last name for the record.

25 THE WITNESS: John Clifford Houghton.

1 THE CLERK: Spell your last name, please.

2 THE WITNESS: H-O-U-G-H-T-O-N.

3 MR. STERNBERG: Members of the jury, your Honor, may I
4 proceed?

5 THE COURT: Please.

6 DIRECT EXAMINATION

7 BY MR. STERNBERG:

8 Q. Mr. Houghton, could you please give us a little background
9 about yourself, tell us where you grew up?

02:10 10 A. Sure. I was born in England and grew up in England. I
11 worked in the pharmaceutical industry, started in England, and
12 worked for several large pharmaceutical companies.

13 Q. Did you go to school in England?

14 A. Yes, I went to school in England. University as well. I
15 went to Liverpool University.

16 Q. If you could take us through your work history after
17 university.

18 A. Sure. After leaving university, I joined Lederle
19 Laboratories, which is an international company that's now
02:11 20 Wyeth and Pfizer. I worked as a sales representative for them,
21 and then became a regional sales manager. And then I joined
22 Rhone-Poulenc Rorer.

23 Q. Can you give us approximate times?

24 A. Yes. I was five years with Lederle and then joined
25 Rhone-Poulenc Rorer.

1 Q. About what year did you join --

2 A. 1987.

3 Q. Take us forward from 1987.

4 A. So from 1987 I was with Lederle, and then around about
5 1992 I joined Rhone-Poulenc -- Rhone-Poulenc Rorer, again
6 started in sales, but then progressed to sales management.

7 Q. Sales of what kinds of products?

8 A. Pharmaceutical products, drugs, and hospital products as
9 well, and also primary care products, physician products.

02:11 10 After about a year working in the sales team I became a
11 sales manager, so I managed sales representatives in the U.K.,
12 and after about a year and a half of doing that, staying with
13 Rhone-Poulenc Rorer, I was asked to go into head office.

14 I moved into head office, which was in the U.K. at the
15 time, working in sales information, which essentially managed
16 the sales information for the organization and also the
17 incentive schemes for the representatives; spent about a year
18 and a half, two years doing that, and then moved into
19 commercial operations, still with Rhone-Poulenc Rorer as
02:12 20 business manager for commercial ops. And then I moved into a
21 more pure marketing role, essentially to launch a drug in the
22 U.K. This was the first country outside of the U.S. that was
23 going to launch this particular drug.

24 Q. Was drug product?

25 A. It was Nasacort for allergic rhinitis.

1 Q. That's a nose issue?

2 A. Yes, for allergies. Yes.

3 I successfully did that, and based on some of that success
4 interacted with my colleagues in the global team which was at
5 that point with -- Rhone-Poulenc was based in Paris, and
6 France. They had asked me to join them in Paris as an
7 international marketing director working on Nasacort. At the
8 time I declined to do that, but then the company reorganized
9 and there was a merger announced between Hoechst Marion Roussel
02:13 10 and Rhone-Poulenc Rorer. And they were moving head office --
11 global head office from Paris to Bridgewater in New Jersey. So
12 the detraction became a little more attractive for us to move
13 to the States.

14 So my wife and my one child -- this was in the end of
15 1999 -- moved to the U.S. to take up a position as
16 international product director for Nasacort globally. Moved to
17 Bridgewater --

18 Q. As international product director, can you give us an idea
19 of what you did day to day?

02:13 20 A. Yeah, my day-to-day role was managing the global strategy
21 for the product. The product was to be launched in multiple
22 countries. So beyond, you know, managing that strategy, it was
23 also managing the future strategy of the product, what other
24 indications could we be looking at with Nasacort, any line
25 extensions. All of that was managed through me as the

1 commercial person working with my colleagues in clinical, and
2 also regulatory and quality, to bring this product through in
3 other areas and grow the brand. That was more in the strategic
4 side.

5 On the operational side, I was more involved in making
6 sure that all the countries that were able to launch the
7 product had the tools they need to launch the product in their
8 countries. So I did a lot of traveling internationally to meet
9 with my international colleagues to ensure that the product was
02:14 10 successfully launched across the globe.

11 Q. And how long were you with this product?

12 A. That was about -- I've been with the product in the U.K.
13 obviously prior to it being launched in the U.K., and I spent
14 in the U.S. -- from what I recall, it was about a year, year
15 and a half in the U.S. -- managing it globally.

16 Q. What was your next position?

17 A. My next position was new products commercialization,
18 working on the Aventis -- because by now the company has merged
19 and become Aventis -- the Aventis Millennium collaboration,
02:15 20 which Millennium at this point was based in Boston. So my role
21 there was to provide commercial support and guidance and
22 strategy to the discovery and development teams in both Aventis
23 and Millennium of how, as a combined portfolio products that we
24 were developing and discovering together, which indications,
25 which diseases should be the ones that we should be targeting.

1 Q. So at this point you're working with products that are in
2 development as opposed to products that are on the market?

3 A. Correct. All of the products were in both discovery and
4 development. So some of them were way, way back, still working
5 on computer screens with them. So it was discovery and
6 development.

7 Q. But with Nasacort you were working on a product that was
8 already on the market, approved by the FDA, being marketed?

9 A. Yes. Yes.

02:15 10 Q. Take us through with your Aventis-Millennium group.

11 A. Yeah, that was -- I think that lasted about a year, year
12 and a half, and then we had a reorganization back in Aventis.
13 So I was the Aventis-Millennium commercial lead. And when we
14 reorganized, I became the head of respiratory and inflammation,
15 which included the Aventis-Millennium collaboration. So now
16 not only now did I have responsibility for the products and
17 discovering development that were part of Aventis and
18 Millennium collaboration, but also products that were Aventis
19 only, in respiratory and inflammation. And did that, I recall,
02:16 20 again, about two years.

21 And then at that point, because I had been quite
22 successful in managing that portfolio of products predominately
23 in the U.S. -- the discovery teams were based in the U.S. and
24 here in Boston -- I was asked to sort of repeat that process
25 but working on the cardiovascular, metabolism and thrombosis

1 products, which that discovery and development was undertaken
2 in Frankfurt.

3 I didn't move to Frankfurt, but I had to spend a lot of my
4 time traveling to Frankfurt to work with the discovery and
5 development sites there.

6 Q. Frankfurt, Germany?

7 A. In Germany, yes. Sorry about that.

8 That only lasted for a short period of time because Sanofi
9 decided to buy Aventis. So at that point the company
02:17 10 reorganized again. I was involved in working on that takeover
11 and providing portfolio analysis for that. The company was
12 taken over; I was offered a position in Paris, again. Nothing
13 against going to Paris, but we liked it here in the States and
14 didn't want to move to Paris, so we decided to stay here in the
15 USA. Initially, I started working for the U.S. domestic team
16 in Bridgewater for Sanofi.

17 Q. What year is this now?

18 A. That was 2004. Yeah. Yes.

19 And I did that -- I implemented the new products team
02:17 20 there, the commercialization team, put that in place and helped
21 them through that merger, but I didn't get a warm feeling from
22 the job that I was doing. I was just dissatisfied with it. I
23 wanted to do something different. And it just coincided with
24 the time I received a phone call from a recruiter requesting --
25 you know, that they have this position at Stryker Biotech and

1 would I be interested.

2 Q. And how did you go about pursuing the position at Stryker
3 Biotech?

4 A. I said I would be interested and I'd like to put my name
5 forward, which I did. And, you know, usually the way forward
6 then is your resumé is sent to the company. If the company
7 likes what they see, then they'd invite you for interview, and
8 they did. So I came up here to Boston for interview.

9 Q. Who did you interview with?

02:18 10 A. I recall Mark Philip, David Renker, Sau Gee Yung, Judith
11 Sernatinger, Bernadette Alford and Sandy Eltringham and Steve
12 Koenigsberg. They're the only ones that I recall.

13 Q. At some point in early 2005 did you take a position at
14 Stryker Biotech?

15 A. I did, yes.

16 Q. What position did you take?

17 A. I assumed the role of global vice president of global
18 marketing and strategic planning.

19 Q. That was in --

02:19 20 A. February of 2005.

21 Q. Can you generally tell the jury what that title meant?
22 Again, what would you do day to day, week to week?

23 A. Yeah. My understanding -- and certainly what was in the
24 job description -- was to manage the global marketing strategy
25 for Stryker Biotech, the division. That involved both products

1 that were in line; i.e., being promoted or being available for
2 use, but also products that were in development. So that was
3 one key part of my role. And that was globally. So not just
4 in the U.S. but also in Europe, Japan, Asia, et cetera. That
5 was one of my roles.

6 The other part of my role was obviously not just looking
7 at products within our portfolio but also looking for products
8 outside of Stryker Biotech that we might want to acquire or
9 license in or bring into the portfolio. So I had a business
02:20 10 development role and a global marketing role as well.

11 Q. You mentioned a couple of different types of products
12 there. One was products that Stryker Biotech already had and
13 was selling at the time?

14 A. Uh-huh.

15 Q. And then -- you have to use words.

16 A. Yes.

17 Q. Yes?

18 A. Yes. Sorry. Yes.

19 Q. And then products that were in development at the time?

02:20 20 A. Yes.

21 Q. Can you tell us, when you joined Stryker Biotech in
22 February of 2005, what products were then on the market?

23 A. As I recall, OP-1 Implant was available in the U.S.; OP-1
24 Putty was available in the U.S.; Osigraft, as it was called,
25 the same as OP-1 Implant, was available in Europe and

1 Australia.

2 Q. Can you refine your answer to what was available in the
3 U.S. at the time?

4 A. TCP Putty, as it was known. I do not recall if it was
5 already launched or not when I joined, but whilst I was there I
6 remember we changed the name to "Calstrux," and then that
7 became launched.

8 Q. So TCP Putty and Calstrux are one and the same?

9 A. Are the same, yes.

02:21 10 Q. So when you got to Stryker Biotech in February 2005, there
11 were three products on the market?

12 A. Yes.

13 Q. OP-1 Implant, OP-1 Putty, and Calstrux?

14 A. I believe -- it was TCP Putty then. From what I recall, I
15 believe it was available.

16 Q. When you started at Stryker Biotech, who did you report
17 to?

18 A. Mark Philip.

19 Q. What position did he have?

02:21 20 A. He was the president and CEO of Stryker Biotech, the
21 division.

22 Q. And you mentioned a bunch of names, people who you
23 interviewed with. Can you tell us who were the other senior
24 executives at the company when you joined?

25 A. Yes. To the best I remember, Bernadette Alford was the

1 vice president of regulatory; Judith Sernatinger was the vice
2 president of quality assurance; Sau Gee Yung was the vice
3 president of operations; Dean Falb was the vice president of
4 development, discovery and development; David Renker was the
5 vice president of human resources; and --

6 Q. Who was managing the sales force day to day at that point?

7 A. At that point -- yes, at that point Ken Reali was the vice
8 president of sales.

9 Q. Did that change while you were at Stryker Biotech?

02:22 10 A. It did, yes.

11 Q. To whom?

12 A. To me.

13 Q. And how long were you at Stryker Biotech?

14 A. I'd been there three months, I think it was, I seem to
15 recall. So this was now in the -- sort of the
16 April-June -- sort of June period. And I was offered the
17 position of -- they expanded my role, basically. So going from
18 global marketing and strategic planning, my new title was
19 global sales and marketing.

02:23 20 Q. So in June of 2005 when you take over the sales in the
21 U.S. as well, how was your sales team organized?

22 A. At that time I implemented a restructuring.

23 Q. Can you tell the jury about that restructuring?

24 A. Yeah. From what I recall, when I took over there were two
25 regional directors, one for the east, one for the west, and

1 then beneath those two regional directors were the
2 representatives. And, again, from what I'm recalling --
3 because it wasn't my structure, but from what I'm recalling --
4 it was two regions reported into the east and two into the
5 west. That's how I seem to think it was.

6 Q. Is that how you restructured it?

7 A. No.

8 Q. How did you restructure it?

9 A. I restructured it -- I brought it in line to reporting to
02:23 10 one person, which would be the -- you know, the U.S. director
11 of sales.

12 Q. Who was that?

13 A. I promoted Bill Heppner to that role. And then beneath
14 Bill we implemented having four regional managers in place at a
15 regional level.

16 Q. Who were they?

17 A. At that time Jeff Whitaker, Dave Ard came on a little bit
18 later but he ultimately became one of the regional managers,
19 Peter Murphy and Ryan Denney.

02:24 20 Q. Roughly organized east, south, central and west?

21 A. Roughly, yes.

22 Q. And Mr. Heppner was managing those four regions?

23 A. Correct.

24 Q. So by February 2005 you'd been in the pharmaceutical and
25 medical industry for about how long?

1 A. I started in '87. So, yeah, 20 years nearly.

2 Q. Twenty years?

3 A. Yeah.

4 Q. And was the sales organization that you put into place
5 with the national sales director, the regional managers, a type
6 of sales organization that you were familiar with from your
7 experience?

8 A. Yes.

9 Q. When you made this reorganization in roughly June of 2005,
02:25 10 how many sales representatives were there working under
11 Mr. Whitaker, Mr. Ard, Mr. Denney and Mr. Murphy?

12 A. Yeah, it was roughly seven to eight for each, so around 30
13 sales representatives --

14 Q. And --

15 A. -- in total.

16 Q. How were they configured geographically?

17 A. Again, it was seven to each region. So roughly seven on
18 the west coast, seven in the central, seven representatives in
19 the south and seven in the east.

02:25 20 Q. Your office was where?

21 A. In Hopkinton, Massachusetts.

22 Q. About how many people worked in the Hopkinton office of
23 Stryker Biotech?

24 A. A hundred and twenty, possibly.

25 Q. Where was Stryker Biotech's manufacturing facility?

1 A. We had -- the main manufacturer was in Lebanon, in New
2 Hampshire.

3 Q. What was manufactured there?

4 A. The protein, BMP.

5 Q. That was part of the --

6 A. Part of OP-1, yes.

7 Q. Mr. Houghton, can you tell the jury a little bit about why
8 you decided to go to work for Stryker Biotech?

9 A. You know, when I interviewed with Mark Philip -- I mean,
02:26 10 obviously, you look to your boss to give you an idea where he
11 wants to take the company and the vision for the company. And,
12 you know, Mark had described to me that he wanted Stryker
13 Biotech to become one of the bigger divisions of Stryker, so
14 there was some ambition there. He also described to me that,
15 you know, maybe someday Stryker Biotech could become a
16 standalone company and trade publicly on its own. So I felt
17 there was a lot of ambition there.

18 And he gave me the opportunity to start with a blank piece
19 of paper. When I joined the company, directly reporting to me
02:26 20 were four people. There was no real marketing structure, as I
21 would call a marketing structure, and no real structure to the
22 strategic side as well. So it really seemed to be a blank
23 canvas for me to, you know, implement 18 years of my experience
24 and build the company with Mark.

25 Q. What excited you about the products, about the OP-1

1 products?

2 A. What excited me was the potential for these products. You
3 know, obviously, they treat very debilitating circumstances.
4 And patients who are in a lot of pain, you bring a lot of
5 relief to them. But also, the future of these products, you
6 know, to grow bone, to grow cartilage, and not to have to go
7 through some of the mechanical approaches to dealing with their
8 pain. But actually using a product like OP-1 to help with that
9 was something I thought was exciting for the patient, also for
02:27 10 the company.

11 Q. Mr. Houghton, I would like to show you some of these
12 products.

13 MR. STERNBERG: Your Honor, may I approach?

14 THE COURT: Yes.

15 BY MR. STERNBERG:

16 Q. Mr. Houghton, if you would take these in numerical order,
17 Exhibit 86. Do you see it? It has a yellow sticker on it. 86
18 for identification purposes.

19 A. I guess I'll need my glasses. Yup.

02:29 20 Q. What is Exhibit 86?

21 A. This is an OP-1 Putty. This is what was the
22 representatives were using [sic] to the surgeons.

23 MR. STERNBERG: I offer Exhibit 86.

24 MR. O'CONNOR: No objection.

25 THE COURT: No objection? All right.

1 (Government Exhibit No. 86 received into evidence.)

2 BY MR. STERNBERG:

3 Q. Mr. Houghton, can you open the box and show us the vials
4 that are in there?

5 A. (Witness complies.)

6 Q. The larger of the two vials, the one in your left hand,
7 hold that up?

8 A. (Witness complies.)

9 Q. What is that?

02:29 10 A. This is the cellulose, the reconstitution that you put
11 with the OP-1 Putty.

12 Q. Is that the powder that is meant to grow the bone?

13 A. No. I believe this is the powder that is meant to grow
14 the bone.

15 Q. The smaller of the two vials?

16 A. Yes.

17 Q. The one that says "OP-1 additive"?

18 A. No, the other way around. Yeah, this is the OP-1 Putty;
19 this is the additive.

02:30 20 Q. The smaller vial is the additive?

21 A. Yeah.

22 Q. And those two together are what is OP-1 Putty?

23 A. Yes.

24 Q. Take a look, please, at the box marked Exhibit 85 for
25 identification.

1 A. Yes.

2 Q. What is that?

3 A. This is OP-1 Implant.

4 MR. STERNBERG: I'd offer Exhibit 85.

5 MR. O'CONNOR: No objection.

6 THE COURT: No objection? All right.

7 (Government Exhibit No. 85 received into evidence.)

8 BY MR. STERNBERG:

9 Q. Would you open up that box, Mr. Houghton?

02:30 10 A. (Witness complies.)

11 Q. How many vials are in there?

12 A. Just one.

13 Q. Would you take it out, please? What is that?

14 A. This is the OP-1 Implant --

15 Q. And --

16 A. -- which is the BMP7 that is in there.

17 Q. So for the OP-1 Implant that is in the box, that comes
18 with just one vial?

19 A. Correct.

02:30 20 Q. What was OP-1 Implant? What kinds of additions was OP-1
21 Implant meant to treat?

22 A. It was for tibial nonunions.

23 Q. What about OP-1 Putty?

24 A. For spinal implants.

25 Q. What kind of FDA approval did OP-1 Implant and OP-1 Putty

1 have?

2 A. Both of them had what is called the HDE.

3 Q. Is "HDE" shorthand for "humanitarian device exemption"?

4 A. It is.

5 Q. When you got to Stryker Biotech, or before you took the
6 job at Stryker Biotech, did you know that those products had a
7 humanitarian device exemption?

8 A. I did.

9 Q. And either before getting to Stryker Biotech or after you
02:31 10 got there, what did you learn were the restrictions of a
11 humanitarian device exemption?

12 A. What I understood the restrictions to be is that there was
13 a limit on the number of patients that the product could be
14 used in in an annual period.

15 Q. What limits did you learn?

16 A. 4,000.

17 Q. Who did you learn that restriction from?

18 A. From regulatory, from Bernadette Alford, but also from,
19 you know, talking to Mark Philip and most of the other
02:32 20 executives when I was interviewed. You know, they had told me
21 at the interview that there was a limit on the HDE.

22 Q. When you got to Stryker Biotech what, if anything, did you
23 learn about something called an "institutional review board"?

24 A. I learned that before any clinical trial can be undertaken
25 at an institution, then the institutional review board would

1 have to review the trial, and that is to protect the patient.
2 That is why they have all of these.

3 Q. While you worked at Stryker Biotech, what did you learn
4 about whether Stryker Biotech was attempting to get a different
5 form of FDA approval for OP-1 Putty?

6 A. We were attempting to get a PMA.

7 Q. "PMA" stands for what?

8 A. Premarket approval.

9 Q. Why?

02:33 10 A. Because that's a full approval with no patient
11 restrictions. It's for an indication on -- any patient that
12 comes in with that indication, the product can be used for.

13 Q. While you worked at Stryker Biotech, was there any other
14 product on the market that was a bone morphogenic protein that
15 had full PMA approval?

16 A. Yes.

17 Q. What product was that?

18 A. InFuse by Medtronic.

19 Q. Mr. Houghton, I would like to show you what we've marked
02:33 20 for identification as Exhibit 92. Do you see that on your
21 screen?

22 THE COURT: No, he doesn't yet. I have to know to
23 whom I should expose these things. If this is for the witness
24 only first and then to the jury, let me know that. If it's
25 agreed exhibits, we can skip the step and go directly to the

1 jury, so...

2 MR. O'CONNOR: Your Honor, Mr. Sternberg has not given
3 me a copy, so obviously I need to see it before --

4 THE COURT: All right.

5 MR. STERNBERG: At this point witness and counsel,
6 your Honor.

7 THE COURT: Fine.

8 MR. O'CONNOR: Thank you.

9 BY MR. STERNBERG:

02:34 10 Q. Do you see --

11 THE COURT: You're using the document camera? I'm
12 sorry. Wrong feed. There you are.

13 BY MR. STERNBERG:

14 Q. Mr. Houghton, do you see Exhibit 92 for identification?

15 A. I don't see "92" anywhere, but I see an exhibit in front
16 of me.

17 Q. I'll show you --

18 A. Oh, there it is. Now I see it, yes.

19 Q. What is Exhibit 92 for identification?

02:34 20 A. This is the package insert for OP-1 Putty.

21 MR. STERNBERG: I offer Exhibit 92.

22 MR. O'CONNOR: No objection.

23 THE COURT: Okay.

24 (Government Exhibit No. 92 received into evidence.)

25 THE COURT: Do you want it displayed?

1 MR. STERNBERG: Please.

2 BY MR. STERNBERG:

3 Q. Mr. Houghton, you just said it was the package insert?

4 A. Yes.

5 Q. Is that also known as a label?

6 A. Yes.

7 Q. And is this a piece of paper that comes in the box of OP-1
8 Putty?

9 A. Yes.

02:35 10 Q. Do you see the first paragraph of Exhibit 92 is called
11 "humanitarian device"?

12 A. Yes.

13 Q. And then at the last sentence of that paragraph it says,
14 "The effectiveness of OP-1 Putty for this use has not been
15 demonstrated." Do you see that under the yellow line?

16 A. Yes.

17 Q. What does that mean?

18 MR. O'CONNOR: Objection, your Honor.

19 THE COURT: Well, let me see you briefly.

02:35 20 Actually, do you know what? We're about at a recess
21 anyway. So why don't we excuse the jurors and I'll hear from
22 you and then we'll come back after the recess.

23 We'll take the morning recess, we'll stay briefly with
24 the lawyers, and then we'll come back with the jurors.

25 THE CLERK: All rise for the Court and the jury. The

1 Court will take the morning recess.

2 (The jury exits the courtroom at 11:13 a.m.)

3 THE COURT: Okay. I guess what's -- we have to
4 understand what the purpose of the offer is. Obviously, the
5 witness -- I think it's obvious the witness can't interpret the
6 FDA regime for us, necessarily. He can give us his
7 understanding. And so I guess that's the question, is his
8 understanding particularly.

9 MR. STERNBERG: His understanding if this is the
02:37 10 exemption from the effectiveness requirements.

11 MR. O'CONNOR: Your Honor, should we be doing this in
12 front of the witness?

13 MR. ULLMANN: Yeah.

14 THE COURT: Okay. Mr. Houghton, would you step
15 outside, please?

16 (The witness is excused.)

17 THE COURT: All right. Go ahead, Mr. Sternberg.
18 What's the purpose of the question?

19 MR. STERNBERG: I want him to explain his
02:37 20 understanding of the exemption from the effectiveness
21 requirements that the FDA ordinarily imposes for premarket
22 approval: The humanitarian device exemption exempts the
23 manufacturer from the effectiveness requirements.

24 MR. O'CONNOR: Your Honor, they don't, number one.
25 And the law is the law. I mean, as I said in my opening

1 yesterday, there is some effectiveness requirement in the HDE
2 requirements.

3 You know, the government -- this business about cap,
4 you know, let it go. It's not correct what he said, all right?
5 So it's just like the criminal misbranding on the slides and
6 now we're going to, you know, there's no effectiveness element.
7 We're going to get it from the witness from reading this on a
8 labeling. It shouldn't be. You know, the requirements are
9 what they are. They have FDA folks on their witness list and
02:38 10 maybe --

11 THE COURT: Well, I guess -- no, I understand that and
12 I agree that it cannot be substantive evidence of what the FDCA
13 requires. So what I want to hear is why it matters what the
14 witness thinks it means, I guess, is the question.

15 MR. STERNBERG: The witness is joining a company that
16 has two products with limited approvals, and there's another
17 competitor on the market that has full approval. His
18 understanding of why their approvals are different from and
19 less than the other.

02:39 20 THE COURT: By why does his
21 understanding -- subjective understanding, I think is the
22 question -- why does his subjective understanding matter? It
23 may matter what the regime is, and the jurors may have to be
24 told at some time either by myself or through a qualified
25 expert witness what the regime is. He has not yet been

1 qualified to do that, so all he can say is what he thought it
2 meant. And so I guess that's the question: What's the
3 relevance of what he thought it meant?

4 MR. STERNBERG: We can move away from it, your Honor.

5 THE COURT: Okay. All right. We will.

6 MR. O'CONNOR: Thank you, your Honor.

7 THE COURT: Okay. We'll take the morning recess.

8 MR. O'CONNOR: Thank you.

9 THE CLERK: All rise. The Court will take the recess.

02:39 10 (The Court exits the courtroom and there is a recess
11 in the proceedings at 11:17 a.m.)

12 (After the recess:)

13 THE CLERK: Counsel, if you could do me a favor. When
14 you're questioning, keep your voice up. Jurors aren't hearing,
15 okay?

16 All rise for the Court and the jury.

17 (The Court and the jury enter the courtroom at
18 11:42 a.m.)

19 THE CLERK: Be seated.

03:05 20 THE COURT: Continue.

21 BY MR. STERNBERG:

22 Q. Mr. Houghton, before we broke, you told us that OP-1 was
23 manufactured in New Hampshire?

24 A. Yes, sir.

25 Q. How did the OP-1 get from New Hampshire to hospitals

1 around the country where it was used?

2 A. It was packaged in Hopkinton, in Massachusetts. Then it
3 was distributed from Hopkinton, initially from Hopkinton
4 direct. And then later on, we implemented a hub system where
5 we distributed to hubs and they then sent it to the hospitals.

6 Q. When you talk about hubs, what do you mean?

7 A. Local warehouses, is the best way I can describe it, you
8 know, that could hold the product in the condition that the
9 product had to be held in.

03:06 10 Q. What conditions were those?

11 A. The temperature was supposed to remain at zero degrees.
12 It wasn't supposed to go above zero. Temperature control.

13 Q. While you worked at Stryker Biotech, did Stryker Biotech
14 sell OP-1 both on consignment and as a straight purchase?

15 A. As I recall, yes.

16 Q. Can you explain to the jury the difference between a
17 consignment order and a straight purchase order.

18 A. Straight purchase order, my understanding, is that the
19 order was made and then there would be a financial transaction
03:06 20 directly for however many units they purchased, four, five,
21 however many they would purchase.

22 A consignment, they would receive the product without
23 paying for it. But then when they would use it -- they would
24 hold it at the hospital. And then when they used it, that's
25 when the cash transaction would take place.

1 Q. For most of the OP-1 business, was it consignment or
2 straight purchase?

3 A. I don't recall the exact percentage. What I do recall is
4 that initially there was more consignment than I was
5 comfortable with. So we -- that's why we implemented the hub
6 system: to enable faster distribution of the product so we
7 didn't need to have as much consignment.

8 Q. On the straight purchase, if the hospital wanted to order
9 one unit of OP-1 --

03:07 10 A. Um-hum.

11 Q. -- and just purchase it directly --

12 A. Yes.

13 Q. -- they would just pay the -- what was it? \$5,000?

14 A. The OP-1 Implant was 5,000 and the OP-1 Putty was 5,250.

15 Q. So there would be an exchange of money for product right
16 away?

17 A. Correct.

18 Q. On a consignment basis, the product would sit in a
19 refrigerator at the hospital --

03:07 20 A. Yes.

21 Q. -- unpaid for --

22 A. Yes.

23 Q. -- until it was used?

24 A. Yes.

25 Q. And then once it was used, can you tell us about the

1 process by which Stryker Biotech would find out it had been
2 used and, therefore, know how to bill the hospital?

3 A. Yes. The hospital would notify that they had used it in
4 that surgery, usually through fax machine or however best
5 direct communication we had. And then that would be billed.

6 Q. While you worked at Stryker Biotech, did you ever attend
7 any surgeries involving the use of OP-1?

8 A. I recall one that I attended where it was used.

9 Q. Tell us about that.

03:08 10 A. It was a spine surgery in Philadelphia. And I believe
11 that one unit of OP-1 was used in that spine surgery.

12 Q. One unit of OP-1 was used in the spine surgery?

13 A. Yes.

14 MR. O'CONNOR: Objection. And you know --

15 THE COURT: Yes. Sustained. I'll strike that. Lack
16 of foundation.

17 BY MR. STERNBERG:

18 Q. How did you know how many units of OP-1 had been used in
19 the spine surgery that you observed?

03:08 20 MR. O'CONNOR: Objection. In the question, that it
21 was. I mean --

22 THE COURT: No. Overruled. He may answer that.

23 THE WITNESS: I'm sorry. Can you repeat that.

24 BY MR. STERNBERG:

25 Q. How did you know how many units of OP-1 had been used in

1 the spine surgery that you observed?

2 A. I recall seeing one box of the OP-1 there. So what I
3 recall was what I saw: one box. And I don't recall if more
4 were used. I recall one was used.

5 Q. Were you -- Who else from Stryker Biotech was with you at
6 that surgery?

7 A. From what I recall, Peter Murphy was with me that day.
8 And I believe -- I don't recall the representative that was
9 also there. I can't recall his name. But there was a

03:09 10 representative there as well from the Pennsylvania area.

11 Q. Why were you there observing that surgery?

12 A. To increase my knowledge, to have a better understanding
13 of what happens in the surgery.

14 Q. How much of the surgery did you observe?

15 A. I observed three operations -- four operations in total.

16 Q. Over the course of how many days?

17 A. One day.

18 Q. About how long were the surgeries that you observed?

19 A. Probably an hour each.

03:10 20 Q. Performed by the same or different surgeons?

21 A. The same surgeon.

22 Q. Who was that?

23 A. Alex Vaccaro.

24 Q. During these surgeries that you observed --

25 A. Yes.

1 Q. -- what, if any, other Stryker Biotech products were used?

2 A. I don't recall any other Stryker Biotech products being
3 used in that surgery.

4 Q. You may have already mentioned this. If you did, I
5 apologize. What kind of a surgery was it?

6 A. There were four different surgeries. The first one was a
7 posterior on the neck area.

8 Q. "Posterior" means --

9 A. The back.

03:10 10 Q. -- the backside?

11 A. Yes. On the spine at the top. Then went next door and
12 the patient had been prepped for another spinal surgery, but
13 lower in the lumbar area. Then went next door and saw the next
14 one, which again, I believe, was another spine surgery. And
15 they were using a new disk that had been developed by Johnson &
16 Johnson in that surgery. And then we went back to the first
17 person, who they'd flipped over and were doing an anterior.

18 Q. All four with OP-1 Putty?

19 A. No. Only one.

03:11 20 Q. How many with OP-1 Putty?

21 A. From what I recall, only one.

22 Q. While you were at Stryker Biotech, what was Stryker
23 Biotech doing to try to get premarket approval for OP-1 Putty?

24 A. We had undertaken --

25 MR. O'CONNOR: Objection. Foundation.

1 THE COURT: Overruled.

2 THE WITNESS: I can answer?

3 THE COURT: Yes. You may answer.

4 THE WITNESS: We had undertaken a clinical trial. And
5 we were looking at the results from that trial. At the same
6 time we were looking to start another trial.

7 BY MR. STERNBERG:

8 Q. What other trial?

9 A. Another -- Sorry. Another trial involving OP-1 in a --
03:12 10 either a spinal indication or a trauma indication if it was
11 going to be OP-1 Implant.

12 Q. While you worked at Stryker Biotech -- and by the way,
13 Mr. Houghton, how long did you work at Stryker Biotech?

14 A. I joined in February 2005. My last day in the office was
15 May 15, 2006. And I officially left the company at the end of
16 June 2006.

17 Q. Over the course of those 15 months, what, if any,
18 applications to the FDA did Stryker Biotech make for premarket
19 approval?

03:12 20 A. I don't recall any application being made during that time
21 that I was there.

22 Q. In your job as global sales and marketing director --

23 A. Yes.

24 Q. -- what role did you have in setting budgets for the sale
25 of the Stryker Biotech products?

1 A. The primary role? The process that we had in place was to
2 look at the strategic plan for the next three to five years,
3 look at that at a high level of what kind of numbers we
4 required for development for the factory, all of the aspects of
5 the business, the whole business.

6 And then to break that down then into what that meant at
7 the operational level, both in the U.S. and also in the other
8 countries that were selling product.

9 Q. And confining your answer now just to the United States,
03:13 10 who did you work with to set the budget for United States sales
11 of OP-1 Putty, OP-1 Implant, and Calstrux?

12 A. I worked with the marketing team and also, of course, the
13 sales management team, which was Bill and the four regional
14 managers -- Mr. Heppner.

15 Q. When you say "Bill," you mean Mr. Heppner?

16 A. Mr. Heppner, sorry. Yes.

17 Q. And when you say "the four regional managers," who do you
18 mean?

19 A. Mr. Ard, Mr. Whitaker, Mr. Murphy and Mr. Denney.

03:14 20 Q. In the calendar cycle at Stryker Biotech --

21 A. Um-hum. Yes.

22 Q. -- when did the budgets for, say -- when did the budget
23 for 2006 get developed?

24 A. In October of 2005.

25 Q. When is that budget then presented to the sales force?

1 A. It doesn't get presented normally until the January
2 timeframe as we're coming into that new year. First of all, it
3 has to go to the leadership team, my peers and Mark Philip, and
4 then, of course, it has to be going to corporate Stryker.

5 Q. When you say "corporate Stryker," what do you mean?

6 A. Head office, Kalamazoo Stryker.

7 Q. Kalamazoo, Michigan?

8 A. Yes.

9 Q. The parent company of Stryker Biotech?

03:14 10 A. The parent company of Stryker Biotech, yes.

11 Q. In your 15 months of work at Stryker Biotech, how many
12 annual sales budgets were you involved in preparing?

13 A. From what I recall totally preparing, one.

14 Q. The sales budget for which year?

15 A. 2006.

16 Q. Mr. Houghton, let me show you what we've marked for
17 identification as Exhibit 226. What is Exhibit 226?

18 A. This, according to the title there, is the 2006 sales
19 quotas broken down by individual representatives for OP-1

03:16 20 Putty, OP-1 Implant, and TCP, also known as Calstrux.

21 Q. How do you figure out what numbers to assign to each of
22 the representatives in each of the regions?

23 A. We -- You start with a total number, which is based on
24 historic sales and historic growth rates, look at how that's
25 progressing, total. And that becomes your total number for the

1 year.

2 And then doing that same application at a regional and
3 territory level, individual rep level, looking at how they've
4 been performing and how they're growing. And a lot of that is
5 dependent on how long the representative has been with the
6 company. If they're new, you expect a lower growth rate. If
7 they've been there longer, you'd expect a larger growth rate.

8 So really the total number was developed probably more for
9 myself and for the marketing team, and then breaking it down at
03:17 10 the individual region territory levels was very much with the
11 sales management team.

12 Q. Whose input did you rely on to set both the regional
13 numbers and then, within the regions, the individual
14 representative numbers?

15 A. The sales management team: Mr. Heppner, Mr. Ard,
16 Mr. Whitaker, Mr. Murphy, Mr. Denney.

17 MR. STERNBERG: I offer Exhibit 226.

18 MR. O'CONNOR: No objection here.

19 THE COURT: All right. It's displayed now to the
03:17 20 jury.

21 (Government Exhibit No. 226 admitted into evidence.)

22 BY MR. STERNBERG:

23 Q. Mr. Houghton, at the bottom of Exhibit 226, there's a box
24 that says "Bill Heppner"?

25 A. Um-hum. Yes.

1 Q. And then it goes across and has a series of numbers, one
2 for OP-1 Putty, one for OP-1 Implant, one for Calstrux/TCP, and
3 then a total. What does that row represent?

4 A. That represents the total sales that we were trying to
5 achieve or would hope to achieve in 2006 across the USA.

6 Q. And are those total numbers -- if one were to do the math
7 and add up each of the columns, are they meant to total up?

8 A. I would expect them to. That was the intent, yes.

9 Q. What's the -- In terms of Stryker Biotech's day-to-day
03:18 10 business, what's the internal significance of these sales
11 quotas?

12 A. This -- this is what drives salespeople. They need a
13 target to achieve. And this is something that we would set for
14 them to aim to achieve that on an annual basis. And they would
15 be -- their salary was paid for that, but also they would be
16 bonused depending on whether they achieved this or not.

17 Q. How often did the sales representatives and the sales
18 managers get information about how they were doing relative to
19 their quotas?

03:18 20 A. Regularly. We were fortunate in this situation because we
21 handled all of the direct orders. Sales data and sales
22 information was available within 24 hours, unlike other
23 businesses where it takes a little longer to process that. We
24 wouldn't necessarily provide it to the representatives daily,
25 but usually certainly on a weekly or -- and certainly on a

1 monthly basis, they would receive what they were doing.

2 Q. While you worked at Stryker Biotech, what, if any,
3 concerns did you have about the sales culture?

4 A. Could you be more specific.

5 Q. What, if any, concerns did you have about the sales
6 culture, being focused less on the indication of the
7 products --

8 A. Um-hum.

9 MR. GURNEY: Objection to the leading, your Honor.

03:19 10 THE COURT: Sustained.

11 BY MR. STERNBERG:

12 Q. Mr. Houghton, let me show you what we've marked as
13 Exhibit 214.001 for identification purposes.

14 MR. O'CONNOR: Object. It's a multipage document. We
15 can't even see the first page. And we haven't been given a
16 copy. We need copies.

17 Oh, we've got copies. Thank you, your Honor.

18 Thank you, Jeremy.

19 MR. GURNEY: Do you have a copy for me, Mr. Sternberg?

03:20 20 Thank you.

21 MR. ULLMANN: Your Honor, may we be heard at sidebar
22 about this document?

23 THE COURT: All right.

24 (Discussion at sidebar and out of the hearing of the
25 jury:)

1 MR. ULLMANN: It appears to me that the government may
2 be trying to get in through the back door of part of this case
3 that your Honor severed in -- in severed Count 13.

4 And it seems as if the government is trying to suggest
5 that the only appropriate quota would be something based on
6 this 4,000-patient limit, or cap. First of all, as
7 Mr. O'Connor said, that was not the law -- there is no
8 4,000-patient limit on the number of patients who can be
9 treated with an HDE-approved device.

03:23 10 What the government is trying to do here is lay a
11 foundation and then suggest that on higher sales quotas in
12 later years, they were somehow improper or illegal.

13 I believe that that's a part of the case that the
14 government has already decided is not part of this trial.

15 MR. STERNBERG: If I may. This has nothing to do with
16 statements to the FDA -- any false statements to the FDA or any
17 of the overt acts associated with that that were part of the
18 severance. It's part of the company's budgeting process. And
19 the line of questioning is about the fact that the company
03:24 20 knows that the label for OP-1 Putty says you're supposed to use
21 two units per patient.

22 And the company knows that most of the sales are of
23 one unit because it's too expensive when you sell two units and
24 that the way to solve that expense issue is to mix one unit of
25 OP-1 with one unit of Calstrux in order to make the sale. And

1 the objection to the sale is two units are too expensive. This
2 is the company's own document. It reflects its understanding
3 of its budgeting process.

4 THE COURT: I don't think evidence concerning 4,000
5 patients as a cap or limit is necessarily excluded by the
6 severance of Count 38. Certainly the false statement issue is
7 out. But there may be other proper evidentiary value to the
8 understanding of the HDE exemption. I don't know. So it's not
9 automatic, is what I'm saying.

03:25 10 MR. ULLMANN: I understand the Court's broad ruling.
11 But I'm very sensitive to any use of that limit to suggest
12 wrongdoing by the individual defendants, who have no
13 responsibility for working with the HDE rules and regulations.

14 MR. O'CONNOR: Your Honor -- and I'd just say on
15 behalf of the company -- I understand Mr. Sternberg's
16 rationale. The basis, the relevance point is that the company
17 promoted one unit off label because the label said two units.
18 And the motive -- the motive for promoting one unit instead of
19 two is an understanding that there was some kind of, you know,
03:26 20 problem with 4,000.

21 And if that is the relevance that the government is
22 aiming at, that, from the company's perspective, is okay. But
23 anything else about it, I don't see any other potential
24 relevance. If that's it, that's fine. But I do have
25 concerns --

1 THE COURT: Well, don't -- we'll go one piece of
2 evidence at a time.

3 MR. O'CONNOR: That's why you do it that way. Thanks,
4 your Honor.

5 (In open court:)

6 BY MR. STERNBERG:

7 Q. Mr. Houghton, I'm showing you what's been marked for
8 identification as Exhibit 214.001. Do you see that on your
9 screen?

03:27 10 A. I do.

11 Q. What is Exhibit 214.001?

12 A. It's the sales plan from May 2005, outlining what the key
13 goals are for the plan and the scope of that and giving an
14 overview of what the current situation is.

15 Q. What involvement did you have in preparing the sales plan
16 that is Exhibit 214.001 for identification?

17 A. I don't recall precisely my -- if this was my document.
18 I'm not remembering that. Given it was May 2005, at that point
19 I don't recall if I'd actually taken over fully as the global
03:27 20 sales and marketing VP.

21 I believe Ken Reali was still involved at that point. So
22 I believe I probably saw this document and had some input into
23 this document, but I'm not sure whether I was the owner of this
24 document or whether Mr. Ken Reali was the owner of the
25 document.

1 Q. You had some input into the document?

2 A. Yes. I recall being -- seeing this document, but I don't
3 recall whether it was mine or Ken's.

4 MR. STERNBERG: Offer Exhibit 214.001.

5 MR. ULLMANN: Objection.

6 THE COURT: Well. We've dealt with -- The objection's
7 overruled.

8 MR. O'CONNOR: I don't object subject to my comment at
9 the sidebar.

03:28 10 THE COURT: All right.

11 (Government Exhibit No. 214.001 admitted into
12 evidence.)

13 BY MR. STERNBERG:

14 Q. Mr. Houghton, while you worked at Stryker Biotech, what
15 did you learn about the rate at which sales of OP-1 Putty --
16 Strike that.

17 While you worked at Stryker Biotech, what did you learn
18 about what the label said about how many units were supposed to
19 be used for OP-1 Putty per spinal surgery?

03:28 20 A. My understanding of the label was that the label allowed
21 for two units of OP-1 Putty to be used in the indication that
22 it was indicated for in the spine.

23 Q. Let me show you what's in evidence as Exhibit 92. Do you
24 see in the "Preparation for use" part of the label, it says,
25 "One unit of OP-1 Putty...will be used on each side of the

1 spine"?

2 A. Yes, I see that.

3 Q. And that was your understanding while you worked at
4 Stryker Biotech, that two units should be used per spinal
5 surgery, according to the label?

6 A. Two units could be used, yes.

7 Q. You see the label says, "One unit of OP-1 Putty...will be
8 used on each side of the spine"?

9 A. Um-hum, yes.

03:29 10 Q. From your interactions with the sales force, what did you
11 learn about the frequency with which two units were used in
12 surgeries as opposed to one unit?

13 MR. O'CONNOR: Objection. Hearsay.

14 THE COURT: Sustained.

15 BY MR. STERNBERG:

16 Q. From your interactions with the sales force, what did you
17 learn about how often two units of OP-1 were used in surgeries?

18 MR. O'CONNOR: Objection.

19 THE COURT: Sustained.

03:30 20 BY MR. STERNBERG:

21 Q. While you worked with Stryker Biotech, Mr. Houghton, did
22 you interact with the sales force?

23 A. I did, yes.

24 Q. What kinds of regular interactions did you have with them?

25 A. I had regular meetings with the sales managers of the

1 team: Mr. Heppner, Mr. Ard, Mr. Whitaker, Mr. Denney, and
2 Mr. Murphy. Face-to-face meetings, at least once a quarter.
3 And I had regular phone calls and emails with those gentlemen
4 on a daily basis.

5 Q. What kinds of opportunities did you have to meet with the
6 entire sales force?

7 A. We had conferences. There was an annual sales conference.
8 Or we would call conferences where required, as we did when I
9 first took over the position. We had a sales conference, I
03:31 10 believe it was in June or July of 2005, where we rolled out the
11 new sales force structure and the new compensation plan.

12 Q. In your various interactions with the sales force, what,
13 if any, difficulties did you learn the sales force was having
14 in selling two units of OP-1 Putty per surgery?

15 MR. LIBBY: Objection, your Honor.

16 MR. O'CONNOR: Objection.

17 THE COURT: I'm going to have to see you at the side.

18 (Discussion at sidebar and out of the hearing of the
19 jury:)

03:32 20 THE COURT: I think we're going to have this constant
21 problem of things that might under some circumstances be
22 offered for the truth of the proposition, okay?

23 MR. O'CONNOR: Yes.

24 THE COURT: And might under other circumstances be
25 admissible for something other than the truth of the

1 proposition.

2 MR. O'CONNOR: Yes.

3 THE COURT: This is an example of it. I don't think
4 there's enough of a foundation for this as admissible
5 hearsay -- I mean, it could be. But I think a generalized,
6 "What did he hear from the sales force" is not enough to
7 qualify the out-of-court declarant as somebody authorized, for
8 example, as an agent for the company. I don't know enough.
9 It's just too vague. But I don't know if that's why you want
03:32 10 it. This is my point. I don't know if there's some
11 non-hearsay purpose to some of this. And this is going to
12 happen with documents as well.

13 MR. O'CONNOR: Um-hum.

14 THE COURT: And I'm going to end up explaining that to
15 the jury multiple times, I expect, that this is a limited
16 offer; it's not for the truth but for the fact that it occurred
17 as a statement in a document, so on and so forth.

18 MR. STERNBERG: Many of the statements in many of the
19 documents are part of the admissions. They're statements by
03:33 20 agents, sales representatives.

21 THE COURT: If you had a field report from a sales rep
22 who said, These are my sales, I'm selling 1.3 per person, or
23 whatever it is, that would be a more solid basis for concluding
24 that it's admissible. But a generalized, sort of, out of the
25 cloud of the sales force, I don't think it's enough.

1 MR. STERNBERG: The reason -- and there are documents
2 that the sales analytics team prepared and distributed them,
3 whether intentionally or otherwise, to steer clear of any
4 impingement on the false statement and other issues that have
5 been severed. I'm happy to go back and work with those.

6 But there are specific statements from some employees
7 of Stryker Biotech and some specific conversations he had with
8 employees of Stryker Biotech about these units -- or these
9 issues where he was told -- it was told that it was far less
03:34 10 than two units per patient used, which are part of the
11 admissions.

12 MR. GURNEY: Well, they're not admissions against any
13 of the individual defendants unless those statements were made
14 by them.

15 THE COURT: Well, it could be under the conspiracy
16 theory. So...

17 MR. O'CONNOR: Your Honor, are you going to let
18 801(d)(2)(E), or whatever it is, the provisional? You are?
19 Okay.

03:34 20 (Court reporter interruption.)

21 MR. O'CONNOR: 801(d)(2)(E) is the rule of evidence, I
22 believe, on the *Petrozziello* coconspirator statement.

23 Your Honor, you know, one thing I would like --

24 THE COURT: Let me just say I guess I expect to. I'm
25 not sure, based on -- I guess based on the openings, what I've

1 learned from the openings -- that's not evidence yet -- I kind
2 of assume that the government can get to the threshold of the
3 *Petrozziello* provisional admission level. I assume that.
4 There's not a genuine contest about that. Whether it gets --
5 keeps them in at the end of the case, another story. That's --

6 MR. GURNEY: Even on that basis, we're not even -- not
7 anywhere near that yet based on the questions that have been
8 asked.

9 THE COURT: I would agree as to the body of evidence.

03:35 10 MR. O'CONNOR: Your Honor, one other objection that I
11 think is important here is, you know, foundation. If this is a
12 conversation with a person, that's good. If there's --

13 THE COURT: Well, I think that's my point.

14 MR. O'CONNOR: It's like, you know -- I think it's
15 just a general pronouncement.

16 MR. LIBBY: In fact, your Honor, that was my concern
17 in addition to the other concerns expressed here. I think
18 Mr. O'Connor just put his finger on it. It's just -- we're at
19 the point where this is critical testimony. If we can do this
03:36 20 in a nonleading way, what we're saying is there comes a time
21 when acts happen. In addition to the purpose for which it's
22 being offered, it's a real concern for me. You know, we're
23 just lobbing softballs into the witness.

24 MR. STERNBERG: There are specific conversations that
25 he's, I expect, going to remember with people. There's also

1 things that he learns that he may not be able to tie with a
2 particular person at Stryker Biotech.

3 THE COURT: Depends on how he learns it.

4 MR. O'CONNOR: That's my --

5 THE COURT: Learning it alone isn't enough. I mean,
6 if he learned it through review of figures, if it's something
7 he did, that's different. If it's -- but if it's just vague, I
8 picked it up somewhere, that's not...

9 (In open court:)

03:37 10 BY MR. STERNBERG:

11 Q. Mr. Houghton, while you worked at Stryker Biotech, did you
12 work with someone named Chris Boyer?

13 A. Yes.

14 Q. Who was Mr. Boyer?

15 A. At that time, Mr. Boyer was a member of the marketing
16 team. I don't recall his official title, but he was the
17 product manager for spine.

18 Q. What kind of regular interactions did you have with
19 Mr. Boyer?

03:37 20 A. Daily.

21 Q. Was his office near yours?

22 A. It was, yes.

23 Q. What kinds of things did you interact with him about?

24 A. Strategic planning, clinical trials, you know, marketing,
25 sales force discussions.

1 Q. What kinds of interactions did you have with him about how
2 many units of OP-1 Putty were being used per surgery?

3 A. I recall Mr. Boyer had undertaken an analysis and had
4 arrived at a number that he believed was the number of units
5 being used.

6 Q. What did Mr. Boyer communicate to you about the number of
7 units being used?

8 MR. GURNEY: Objection, your Honor.

9 MR. O'CONNOR: Mr. Boyer is not in the field, your
03:38 10 Honor. Double level -- It's a real hearsay problem.

11 THE COURT: Overruled. I'll allow it.

12 THE WITNESS: Sorry. Say it again.

13 BY MR. STERNBERG:

14 Q. What did Mr. Boyer communicate to you about how many units
15 were being used per patient in surgeries of OP-1 Putty?

16 A. The number he communicated to me was 1.35.

17 Q. While you were at Stryker Biotech, what, if any,
18 communications did you have with anyone else at Stryker
19 Biotech -- Mr. Boyer or anyone else -- that provided you with
03:39 20 any different number?

21 A. There were, I recall, two other individuals that had been
22 working on this analysis prior to me joining Stryker Biotech:
23 Mr. Barnett, Mr. Michael Barnett; and Ms. Sandy Eltringham.
24 And so they had brought to me the conclusions of the analysis
25 that the three of them had been working on.

1 Q. In what range or cluster did their conclusions form into?

2 MR. ULLMANN: Objection.

3 THE WITNESS: The only number I'm recalling --

4 THE COURT: Overruled. Go ahead.

5 THE WITNESS: The only number I'm recalling at this
6 point in time is 1.35.

7 BY MR. STERNBERG:

8 Q. What conversations did you have with them or any other
9 Stryker Biotech employees about why the number was less than
03:39 10 two?

11 MR. O'CONNOR: Objection.

12 MR. LIBBY: Objection, your Honor.

13 THE COURT: Sustained to the form of the question
14 anyway.

15 BY MR. STERNBERG:

16 Q. What, if any, conversations did you have with anyone --
17 with -- let me start with, with Mr. Boyer, with Ms. Eltringham,
18 or with Mr. Barnett about why the number was other than two?

19 MR. O'CONNOR: Objection, your Honor. Compound,
03:40 20 hearsay, no foundation. On those three --

21 THE COURT: No.

22 You may answer it, if you're able to.

23 THE WITNESS: I recall they had formed a presentation,
24 which they brought to me and we walked through the presentation
25 on how they had arrived at the number. And also some of the

1 reasons why the number was what it was.

2 BY MR. STERNBERG:

3 Q. What, if any, reasons did they provide you -- and "they"
4 being Ms. Eltringham, Mr. Barnett, or Mr. Boyer -- as to why
5 the usage wasn't two units per patient?

6 MR. LIBBY: Objection to form, your Honor, as to why.

7 THE COURT: Well, I'm not sure that's...

8 Objection sustained.

9 BY MR. STERNBERG:

03:41 10 Q. What reasons did Mr. Barnett, Ms. Eltringham, and
11 Mr. Boyer give you as to why their analysis came in around 1.35
12 units per patient?

13 MR. O'CONNOR: Objection.

14 THE COURT: I'll have to see you again.

15 (Discussion at sidebar and out of the hearing of the
16 jury:)

17 THE COURT: I think that there's an inadequate
18 foundation if the why is anything other than that's the way the
19 numbers computed. In other words, if they did a computation,
03:41 20 they took sales figures and they divided by units, or whatever,
21 if it's just math, then they can say why. But if it's because
22 surgeons were doing something or sales reps were doing
23 something, I don't know that we have -- maybe he has a
24 foundation, but we don't have that yet.

25 MR. O'CONNOR: These are not people in the field.

1 THE COURT: That's sort of my point.

2 MR. O'CONNOR: These are not people in the field.
3 They're in headquarters and they work for Mr. Houghton at
4 headquarters. They're not out in the field.

5 MR. GURNEY: None of these individuals are alleged to
6 be coconspirators, so no coconspirator exception would apply to
7 allow -- this is all hearsay -- to come in.

8 THE COURT: Well...

9 MR. STERNBERG: The company's relationships --

03:42 10 THE COURT: Right. I think it's because it's an
11 authorized statement by the company.

12 MR. GURNEY: But it wouldn't make it admissible
13 against the individuals.

14 THE COURT: Maybe.

15 MR. STERNBERG: I understand, your Honor, your ruling.
16 We'll take it up with sales.

17 (In open court:)

18 BY MR. STERNBERG:

19 Q. Mr. Houghton, how did you communicate the sales
03:43 20 budget/sales quotas to the field sales force?

21 A. We -- Through their sales managers. I'd say the process
22 was one of top down, working with them and then working with
23 them to communicate that to the sales team. Sorry. Could I
24 just specify. You're referring to the 2006 sales --

25 Q. Correct. Exhibit 226, the sales quotas that are in the

1 2006 --

2 A. Yes.

3 Q. -- Exhibit 226, rather.

4 A. From what I recall, the sales managers discussed this with
5 the representatives, which gave time for feedback so then we
6 could make any adjustments to that. But ultimately, the
7 January sales conference was the time when that was the -- they
8 were sort of set in stone.

9 Q. The January sales conference? What is that?

03:44 10 A. That's when we would come together as a company, all
11 the -- the U.S. sales team and U.S. marketing team with
12 representatives from head office to talk about the year ahead
13 and what the strategy and plans were for the year.

14 Q. Where was that 2006 national sales meeting?

15 A. From what I recall, it was in Phoenix, Arizona.

16 Q. What was your role at that meeting?

17 A. I understood it to be my meeting.

18 Q. What does that mean?

19 A. It was my meeting.

03:44 20 Q. What was going to happen at the meeting that made it your
21 meeting?

22 A. I had set the agenda, obviously with input from my team.
23 We had invited some surgeons to give a presentation. We'd
24 invited the CEO of Stryker to give a presentation as well. And
25 also representatives from head office other than myself would

1 also make presentations on the stage.

2 Q. How many days was the meeting?

3 A. From what I recall, two and a half -- from what I recall,
4 two and a half, three days.

5 Q. And what was the mix between business and pleasure?

6 A. It was -- The mix was mainly business in the daytime. And
7 then in the evenings we would have dinner. So there was some
8 entertainment in that context.

9 Q. While you were there, what kind of presentations did you
03:45 10 give?

11 A. I recall giving a presentation of where we had come from
12 as a company since I joined. And so back in the February
13 2005 -- you know, what has changed, what has happened, what
14 have we implemented. And I put up slides showing my -- the new
15 structure of the organization because we'd brought in a lot of
16 people to support the marketing and sales of our products.

17 Q. Who else from senior management in Hopkinton attended the
18 meeting?

19 A. Again, from what I recall, Mark Philip, the president and
03:46 20 CEO of Stryker Biotech, was in attendance. David Renker, the
21 vice president of human resources. Bernadette Alford, the vice
22 president of regulatory. And Judith Sernatinger, the vice
23 president of quality.

24 Q. What project did you and Bernadette Alford collaborate on
25 at that conference?

1 A. We decided on the -- Sunday morning, I believe, to have
2 a -- the regional meetings. They were -- you know, each of the
3 regional managers were having their own internal meetings. So
4 there were four regional meetings ongoing. We decided to walk
5 around each of those meetings and gain an understanding from
6 the representatives of how things were going in the field.

7 Q. What kinds of things did you learn from the
8 representatives?

9 A. It was specifically targeted --

03:47 10 MR. GURNEY: Objection, your Honor.

11 THE COURT: No. You may have that question.

12 What kinds of things did you learn?

13 THE WITNESS: It was specifically targeted to gain
14 feedback on some adverse event reporting that we had received
15 in Hopkinton in the, I believe remembering, the September
16 timeframe.

17 BY MR. STERNBERG:

18 Q. You say "adverse event reporting." What do you mean?

19 A. I recall that regulatory had received a report that
03:47 20 somebody had had an adverse event with one of our products. In
21 other words, the product had caused something to go wrong in
22 the patient other than what the product should have been used
23 for.

24 Q. And how did you and Bernadette Alford go to these
25 different regional -- what did you do at these different

1 regional breakout sessions to try to find out more information?

2 A. We listened. We --

3 MR. O'CONNOR: Objection, your Honor. Could we see
4 you very briefly at sidebar?

5 THE COURT: All right.

6 (Discussion at sidebar and out of the hearing of the
7 jury:)

8 MR. O'CONNOR: Your Honor, the government has conceded
9 that there's no causation of any adverse events. Mr. Houghton,
03:48 10 I don't know what the prep was -- what just -- said that the
11 company had -- that a product had caused an adverse event.
12 I think it was probably just a slip-up.

13 But I would ask the Court to instruct the jury
14 consistent with how the government's filings have been. That
15 the government is not contending that it can prove or it can't
16 prove that any adverse event was caused by one of these
17 devices.

18 MR. STERNBERG: We're not seeking causation evidence
19 from him.

03:49 20 THE COURT: Well, I think the evidence is later going
21 to contain what the definition of an adverse event is. Perhaps
22 rather than me do it, maybe you can track him back on that.

23 MR. STERNBERG: I'm not sure he knows.

24 THE COURT: Well, I think that may be true. He
25 doesn't know.

1 MR. O'CONNOR: Well --

2 THE COURT: But I don't think at the end of the case
3 the jury will have a misimpression about it. No.

4 (In open court:)

5 BY MR. STERNBERG:

6 Q. Mr. Houghton, you mentioned a series of regional breakout
7 sessions at the 2006 national sales meeting?

8 A. Yes.

9 Q. How many of the regional breakout sessions did you go to?

03:50 10 A. I recall going to at least two of the meetings.

11 Q. After you -- and who accompanied you to each of those
12 breakout sessions?

13 A. My assistant was with me. And also when I arrived at the
14 meeting rooms, you know, Bernadette Alford was in some of those
15 meetings. In other ones, it was the marketing team. It
16 varied.

17 Q. Let me show you what we've marked for identification as
18 Exhibit 107. What's Exhibit 107 for identification,
19 Mr. Houghton?

03:51 20 A. This is a summary of the comments that were received from
21 the regional sales managers and the representatives at the
22 national sales meeting during those walk-around meetings on
23 that Sunday morning.

24 Q. Who prepared Exhibit 107 for identification?

25 A. Bernadette Alford.

1 Q. What draft or preliminary memo did she provide to you?

2 A. I recall this in a draft form being sent to me.

3 Q. What -- Did you have an opportunity to comment on it?

4 A. Yes.

5 MR. STERNBERG: I offer Exhibit 107 for
6 identification.

7 MR. ULLMANN: Objection.

8 THE COURT: Overruled.

9 MR. ULLMANN: Hearsay. Not beyond the identity of who
03:52 10 prepared it is a large amount of the hearsay.

11 THE COURT: Well, okay. There's two levels, actually.
12 And I agree as to the second level. I'll admit the document,
13 which the jurors haven't seen yet, as it reflects what was
14 said. In other words, it's a statement by Ms. Alford or
15 whoever else prepared it that the following comments were made,
16 the fact of the making of the comment.

17 It is not evidence that whatever the comments were
18 were true. And under that limitation, I will admit it and
19 expose it to the jury.

03:53 20 (Government Exhibit No. 107 admitted into evidence.)

21 BY MR. STERNBERG:

22 Q. Mr. Houghton, at the 2006 -- excuse me -- national sales
23 meeting, you had a chance to talk directly with some of the
24 sales representatives?

25 A. Yes.

1 Q. At that time, what did you know about whether Stryker
2 Biotech had conducted any clinical trials of a mixture of OP-1
3 and Calstrux?

4 A. I was not aware of any trials being conducted.

5 Q. Let me back up for a second. Will you explain to us, what
6 is a clinical trial?

7 A. Could I clarify.

8 Q. Please.

9 A. In a clinical trial for registration purposes or a
03:53 10 clinical trial that a physician decides to do under his own
11 IRB?

12 Q. Let's start with the former: clinical trial for what you
13 call registration purposes.

14 A. In order to gain approval via the FDA to have your product
15 label adjusted, depending on what indication you are seeking,
16 then you have to go through a statistically approved clinical
17 trial that the FDA has to approve. If that's approved and the
18 trial is successful -- of course, the product has to achieve
19 the results you set out to achieve -- then the FDA would allow
03:54 20 you to change your label and that would become your new
21 indication for that product.

22 Q. What, if any, role did you have in planning, conducting,
23 overseeing any clinical trials at Stryker Biotech of a mixture
24 of OP-1 and Calstrux?

25 A. No role. We didn't do a clinical trial of those two.

1 Q. What did you learn from the sales -- from the regional
2 sales breakout sessions at the 2006 national sales meetings
3 that prompted you to ask anyone any questions about the company
4 doing a trial?

5 MR. O'CONNOR: Objection.

6 THE COURT: Sustained.

7 BY MR. STERNBERG:

8 Q. What did you learn at the 2006 national sales meeting from
9 your walk-arounds to the regions about the way OP-1 and
03:55 10 Calstrux were being used in the field?

11 MR. O'CONNOR: Objection.

12 THE COURT: Sustained.

13 BY MR. STERNBERG:

14 Q. Did you have particular conversations, Mr. Houghton, with
15 sales representatives about the way OP-1 and Calstrux were
16 being used in the field?

17 A. I'm not recalling any specific or particular discussions
18 with the sales representatives themselves.

19 Q. Did you have any with the sales managers?

03:55 20 A. Yes.

21 Q. Which sales managers?

22 A. Collectively all of the sales management team: Bill -- I'm
23 sorry -- Mr. Heppner and the four regional managers.

24 Q. Mr. Ard, Mr. Whitaker, Mr. Denney, and Mr. Murphy?

25 A. Correct. Yes.

1 Q. In discussions with those five individuals, what did you
2 learn about the way that Calstrux and OP-1 were being used in
3 the field?

4 MR. O'CONNOR: Form. Compound.

5 THE COURT: Overruled.

6 THE WITNESS: I'm answering it?

7 I learned that physicians were choosing to use OP-1
8 with Calstrux.

9 BY MR. STERNBERG:

03:56 10 Q. What did you learn from those five individuals about what
11 role the sales representatives had in discussing the mixture of
12 OP-1 and Calstrux with those physicians?

13 MR. LIBBY: Objection, your Honor.

14 THE COURT: Overruled.

15 THE WITNESS: My understanding from the sales
16 management team is that the reps did not play a role in that.
17 That was the surgeon's decision to decide if he or she wanted
18 to use those two products together.

19 BY MR. STERNBERG:

03:56 20 Q. Who is Chris Ring?

21 A. A sales representative.

22 Q. For Stryker Biotech?

23 A. Yes. Sorry, yes.

24 Q. Mr. Houghton, let me show you what we've marked as
25 Exhibit 12 for identification. What is Exhibit 12 for

1 identification?

2 A. This is Exhibit 111.

3 Q. Excuse me. What is Exhibit 12 for identification?

4 A. This is an email from me to Chris Ring. "Many thanks for
5 the suggestions. I agree with you. I believe" --

6 Q. Before you read it, it's actually two emails, one from
7 Chris Ring to you and then one from you back?

8 A. Yes. There's an original email from Chris Ring to me and
9 then one -- one back from me.

03:58 10 Q. The one back from you is dated what?

11 A. February the 26th. And the one from him is February the
12 15th.

13 MR. STERNBERG: I offer Exhibit 12.

14 MR. O'CONNOR: No objection.

15 THE COURT: Okay. All right. 12 is admitted and
16 displayed.

17 (Government Exhibit No. 12 admitted into evidence.)

18 BY MR. STERNBERG:

19 Q. In the context of the 2006 national sales meeting,
03:58 20 Mr. Houghton --

21 A. Um-hum.

22 Q. -- how soon after that national sales meeting is the email
23 from Chris Ring to you, dated February 15, 2006?

24 A. Approximately two months.

25 Q. Two months?

1 A. Yes. I recall the conference was early January, this
2 is -- Oh, sorry. From him. Month and a half. Yes. Month,
3 month and a half.

4 Q. And Chris Ring tells you that he wants to touch base with
5 you regarding TCP/Calstrux? Those are the same -- that's the
6 same product, right?

7 A. Yes.

8 Q. He tells you, "I think we need training on how to properly
9 implant this product. Like any product, if we have 30-plus
03:59 10 people doing something different with regards to mixing,
11 dosing, et cetera, we are going to see different results."

12 What was your reaction when you saw that?

13 A. I was concerned.

14 Q. Why?

15 A. We had previously, in September, some issues with Calstrux
16 and the reconstitution of the product. And we'd had some
17 adverse reports that there had been some migration of that
18 product.

19 Q. What concerned you about Mr. Ring's statement that if
03:59 20 there are "30-plus people doing something different with
21 regards to mixing, dosing, et cetera, we are going to see
22 different results"? Why were you concerned, if you were
23 concerned, about 30-plus people doing it differently?

24 A. I think we wanted to ensure that the physicians and the
25 surgeons were reconstituting this product as per the label.

1 Q. How many ways does the label suggest to reconstitute the
2 product?

3 A. One way.

4 Q. Your response to Mr. Ring is, "Many thanks for the
5 suggestions. I agree with you. I believe we need to retrain
6 the sales team on how to use Calstrux appropriately. We will
7 be aiming to get something out next week."

8 A. Yes.

9 Q. What -- At this point, February 26, 2006, what training
04:00 10 effort were you undertaking?

11 A. It was still under discussion as to how we were going to
12 do that, given this would be a reminder. Because all the
13 representatives had received training on it, I didn't feel the
14 need to bring the sales team into the head office. So I
15 believe we decided to do it through a teleconference.

16 Q. Do what --

17 A. Do the training through a teleconference.

18 Q. Were you already planning training before you got the
19 email from Mr. Ring?

04:01 20 A. I don't recall that.

21 Q. What -- In this February 2006 timeframe, why were you
22 contemplating doing a sales force training?

23 A. Because as I indicated, we had prior had reports in
24 September and sent a letter in September reminding physicians
25 and surgeons how to reconstitute Calstrux.

1 MR. O'CONNOR: No objection, your Honor. I withdraw.

2 BY MR. STERNBERG:

3 Q. If you'd already sent a letter in September, why were you
4 contemplating something new?

5 A. The letter went to surgeons, and we felt now to remind the
6 representatives as well again so they can pass that information
7 on to the surgeons when they're in the field.

8 Q. Who worked with you on preparing the training that you
9 provided to the sales representatives in the February/March
04:02 10 timeframe?

11 A. In the normal circumstances, the leadership team would
12 comment on all aspects. I recall in this particular aspect,
13 the marketing team that reported to me, but also Bernadette
14 Alford, VP of regulatory; Judith Sernatinger, the VP of QA.
15 And I recall Dean Falb, the VP of R&D was also involved, as
16 well as Dr. Mike Silverman, who was a consultant to the
17 company, acting chief medical officer or VP of medical.

18 Q. What was Dr. Silverman's role?

19 A. He was the acting vice president of clinical.

04:02 20 Q. And in terms of preparing the overall presentation --

21 A. Yes.

22 Q. -- who prepared the documents?

23 A. From what I recall, I prepared the documents, but with
24 everybody's input to those documents.

25 Q. You mentioned in September of 2005, there had been a

1 letter sent out to surgeons?

2 A. Yes.

3 Q. In connection with this training, what, if any, letter was
4 contemplated to be sent to surgeons?

5 A. In connection to this training, it was contemplated that
6 we send another letter to the surgeons reminding them of the
7 reconstitution element, but also the -- reminding them not to
8 use it with OP-1.

9 Q. Let me show you now what we've marked now as Exhibit 111
04:03 10 for identification. Do you see Exhibit 111, Mr. Houghton?

11 A. I can't see the number, but this is the letter I think you
12 put up previously. Yes.

13 Q. What's Exhibit 111?

14 A. This is a draft of the letter that was being proposed to
15 be sent to the surgeons following the training that we were
16 contemplating in the March...

17 MR. STERNBERG: I offer Exhibit 111.

18 MR. O'CONNOR: No objection, your Honor.

19 THE COURT: All right. 111 is admitted.

04:04 20 (Government Exhibit No. 111 admitted into evidence.)

21 BY MR. STERNBERG:

22 Q. Mr. Houghton, you mentioned a letter that was sent in
23 February -- excuse me -- in September of 2005 --

24 A. Yes.

25 Q. -- was a letter about Calstrux?

1 A. Yes.

2 Q. And how is this letter, Exhibit 111 in evidence, different
3 in terms of the products it identified?

4 A. This letter talks about using Calstrux in combination with
5 OP-1 Implant.

6 Q. This letter uses the words "OP-1 Implant"?

7 A. It does, yes.

8 Q. Who is Nebila Idris?

9 A. Nebila Idris was the product manager, I recall, at the
04:04 10 time for Calstrux.

11 Q. How, if at all, was she working on the training and the
12 issues with this letter?

13 A. She would help put together training slides if
14 representatives -- you know, if representatives came into the
15 office for training. She would help with the marketing -- it
16 was her responsibility for the marketing materials that we used
17 in the field. She was the marketing support for Calstrux.

18 Q. In this timeframe, February of 2006, did you ask her to
19 send a draft of this letter out to the sales force to get their
04:05 20 comments?

21 A. I don't believe I did. I don't recall that.

22 Q. Let me show you what we're going to mark -- what is marked
23 as Exhibit 115 for identification, Mr. Houghton. Let's start
24 at the back and work our way forward. Do you know what RSMs
25 are, Mr. Houghton?

1 A. Yes. Regional sales managers.

2 Q. Does Exhibit 115 for identification refresh your memory
3 that in -- on February 14, 2006 or thereabouts, you asked
4 Ms. Idris to send out the draft Dear Doctor letter to the
5 regional sales managers and Mr. Heppner to gain their comments?

6 A. I don't recall the letter being sent to the RSMs. I
7 believe what this is asking the RSMs and Bill for is input to a
8 letter that is anticipated to be sent. The letter that you
9 showed on Exhibit 111, I don't recall that actually being sent
04:07 10 to the RSMs. I don't think Nebi had that letter.

11 Q. So you were asking for comments on the concept of a letter
12 rather than an actual letter?

13 A. That's what I believe that this was inferring, yes.

14 Q. And is Exhibit 115 -- does Exhibit 115 for identification
15 contain some comments that you and Ms. Idris got back on the
16 concept of that letter?

17 MR. LIBBY: Objection, your Honor.

18 THE COURT: Well, first is just a question of whether
19 the document includes that.

04:07 20 You may answer that.

21 THE WITNESS: Sorry, Mr. Sternberg. Could you say
22 that again.

23 BY MR. STERNBERG:

24 Q. Does Exhibit 115 for identification --

25 A. Yes.

1 Q. -- contain comments that you got back from some of the
2 regional sales managers on the concept of a Dear Doctor letter?

3 MR. LIBBY: That's my objection, your Honor.

4 THE COURT: Whether it does?

5 MR. LIBBY: His characterization of a document not in
6 evidence.

7 THE COURT: Overruled.

8 THE WITNESS: The email contains questions that we
9 would want to ask surgeons to understand what was happening,
04:08 10 and as is highlighted from Mr. Whitaker to the team.

11 BY MR. STERNBERG:

12 Q. In other words, Mr. Houghton, you and Ms. Idris wanted to
13 know what kinds of reactions there would be from surgeons in
14 response to a Dear Doctor letter?

15 MR. LIBBY: Objection, your Honor.

16 THE COURT: Sustained to that.

17 THE WITNESS: The intent of this --

18 THE COURT: No. The objection was sustained. We need
19 another question.

04:08 20 BY MR. STERNBERG:

21 Q. What kinds of information were you looking for from the
22 regional sales managers?

23 MR. LIBBY: I object, your Honor.

24 THE COURT: Overruled.

25 THE WITNESS: We were trying to understand what the

1 issues were in greater detail and how we could then present
2 that to physicians so they could understand, this is what we're
3 seeing and this is what we're proposing.

4 BY MR. STERNBERG:

5 Q. In Exhibit 115 for identification, did you get responses
6 that you were seeking from the regional sales managers?

7 A. The response was from Ryan Denney and also from Jeffrey --

8 MR. LIBBY: Objection, your Honor.

9 THE COURT: Overruled.

04:09 10 MR. STERNBERG: I offer Exhibit 115.

11 MR. LIBBY: Object.

12 THE COURT: Overruled. I'll admit it.

13 (Government Exhibit No. 115 admitted into evidence.)

14 BY MR. STERNBERG:

15 Q. So let's start with, on February 14, 2006, Ms. Idris
16 copying Mr. Denney, Mr. Ard, Mr. Murphy, Mr. Whitaker,
17 Mr. Heppner, and then you and some others, asked the RSMs --
18 you told us RSMs is regional sales managers --

19 A. Yes.

04:10 20 Q. -- and Mr. Heppner for their "thoughts and ideas on the
21 type of questions we should anticipate from surgeons and our
22 own sales representatives" --

23 A. Um-hum. Yes.

24 Q. -- from a Dear Doctor letter?

25 A. Yes.

1 Q. And the first response was from Mr. Whitaker. Do you see
2 that?

3 A. Yes.

4 Q. February 14, 2006 at 9:34 p.m.?

5 A. Yes.

6 Q. And he provides some potential surgeon questions and some
7 rep questions?

8 A. Yes.

9 Q. Mr. Houghton, would you please tell us, what were the
04:10 10 potential surgeon questions that Mr. Whitaker provided to you
11 and Ms. Idris and others that he thought would be raised in
12 response to a Dear Doctor letter?

13 MR. O'CONNOR: Objection. It reads --

14 THE COURT: Well, he can read the document.

15 MR. O'CONNOR: He can read it. Okay. I didn't know
16 what was --

17 THE COURT: I think that's what the question was
18 asking, that he --

19 MR. STERNBERG: Yes, your Honor.

04:11 20 THE WITNESS: "What were the adverse events? How did
21 it (Calstrux) perform in your preclinical/clinical trials? If
22 it's migrating or causing increased inflammation, why should I
23 ever use it with" -- alone "or without OP-1? Is this all the
24 product I get (upon seeing the volume of just OP-1 Putty
25 alone)?"

1 BY MR. STERNBERG:

2 Q. Can you pause there for a second, Mr. Houghton. At that
3 point, what, if any, comments had you heard about the volume of
4 OP-1?

5 MR. GURNEY: Objection, your Honor.

6 THE COURT: Overruled.

7 THE WITNESS: OP-1 Implant or OP-1 Putty or generally
8 OP-1?

9 BY MR. STERNBERG:

04:12 10 Q. Well, if the answers are different, tell us.

11 A. I don't recall -- I mean, there is a comment here. I
12 don't recall there being any specific comments about the volume
13 of -- of the product.

14 Q. The next question says, "Why should I use OP-1 now that
15 you don't have a big advantage in handling?" What does
16 "handling" refer to?

17 MR. LIBBY: Objection, your Honor.

18 THE COURT: You may answer.

19 THE WITNESS: My understanding is when -- in a spine
04:12 20 surgery, when the surgeon is placing the putty down each side
21 of the spine, obviously having something that's a very -- can
22 handle well and is very -- like putty, can be very nicely
23 smoothed and put down the side of each spine and remains there,
24 then that's what we're referring to here as the handling, as
25 opposed to it falling apart in their hand or being too hard so

1 they can't do anything with it, not malleable enough.

2 BY MR. STERNBERG:

3 Q. In the next series of questions there's one that says,
4 "This stuff is like wet sand. What can I mix it with (if
5 Implant)?" Do you see that?

6 A. Sorry. I'm not seeing it. Oh. There I see it. Yes.

7 Q. Before February 14 of 2006, had you heard that kind of
8 description of OP-1?

9 A. I had, yes.

04:13 10 Q. From whom?

11 A. From the sales team.

12 Q. Can you give us any particular names?

13 A. I don't recall any particular names. Just from the
14 regular meetings we had and the general discussions around the
15 regional meetings.

16 Q. What, if any, conversations did you have about whether
17 Calstrux could improve the wet sand feeling?

18 A. That was our hope, long term. As a company, the intention
19 was that we wanted Calstrux to become that, you know, matrix
04:14 20 for OP-1 Implant.

21 Q. What did Stryker Biotech have to do in order to realize
22 that dream?

23 A. An FDA-approved clinical trial.

24 Q. More specifically, a clinical trial of what?

25 A. A clinical trial of the two mixed together and used in the

1 particular indication that we were targeting.

2 Q. In February of 2006 or thereafter --

3 A. Yes.

4 Q. -- what, if any, discussions did you have within Stryker
5 Biotech about doing such a clinical trial?

6 A. We'd had many discussions. Strategically we were trying
7 to decide the best path forward here. As I'm sure everybody's
8 aware, clinical trials are expensive, so we needed the budget
9 to do that.

04:15 10 We'd already -- there had been a trial done previously
11 with OP-1, which we were reanalyzing some of those results.
12 But to do another study, we were deciding whether to do a spine
13 study or whether to do a trauma study, how many studies. Do we
14 do it globally, do we just do it in the U.S. All those
15 questions were being discussed at senior management level.

16 Q. At this point, February 2006, what concern did you have
17 that there's no study even planned --

18 MR. GURNEY: Objection, your Honor, to the leading.

19 THE COURT: Sustained.

04:15 20 BY MR. STERNBERG:

21 Q. What concern did you have in February 2006 about the state
22 of any study of OP-1 and Calstrux together?

23 MR. GURNEY: Same objection, your Honor.

24 THE COURT: You may have that.

25 THE WITNESS: No more concern than we needed to do a

1 study. And that's what we required to get a full approval so
2 we could promote the products appropriately.

3 BY MR. STERNBERG:

4 Q. Going on here in Exhibit 115, there are a series of rep
5 questions. Do you see that?

6 A. I do, yes.

7 Q. "Rep" stands for sales representative; is that right?

8 A. It does, yes.

9 Q. Can you start, Mr. Houghton, in this section by -- with
04:16 10 the second question, "Do you know what this is?" And read to
11 us the next few questions.

12 A. "Do you know what this is going to do to our OP-1 sales?
13 Do you know what this is going to do to our Calstrux sales?
14 All my big users mix OP-1 with Calstrux and that's why they use
15 OP-1. How do I keep their business? If I'm in a case tomorrow
16 (with a new user or current user), do I need to tell the
17 surgeon not to mix OP-1 with Calstrux?"

18 Q. Pausing there for a moment, Mr. Houghton --

19 A. Yes.

04:16 20 Q. -- at this point had you heard the term "carrier" with
21 respect to Calstrux?

22 A. Yes.

23 Q. What does "carrier" mean in that context?

24 A. In that context, it was explained to me that there are
25 three legs of a stool essentially for bone growth in this

1 particular area. You need, you know, stem cells. You need
2 something that will signal those stem cells to become bone as
3 opposed to any other type of cell. And you also need some kind
4 of matrix or carrier or -- it had various other names -- that
5 would knit it all together. So that's what I understood the
6 term "carrier" coming from. And you know, Calstrux could be
7 that carrier.

8 Q. Well, based on what you saw in the February 15 --
9 February 14, rather, 2006 email from Mr. Whitaker that's
04:17 10 Exhibit 115 --

11 A. Yes.

12 Q. -- did you come to a view that some of the sales force
13 already viewed Calstrux as a carrier?

14 MR. O'CONNOR: Objection, your Honor. It's leading.

15 THE COURT: Overruled.

16 THE WITNESS: As I indicated, to my understanding of
17 the term "carrier," Calstrux is a carrier. It's a bone void
18 filler, as are some of the other competitors to Calstrux. It
19 just wasn't approved to be the carrier for OP-1.

04:18 20 MR. LIBBY: Objection, your Honor. Move to strike.

21 THE COURT: No. It may stand.

22 BY MR. STERNBERG:

23 Q. Going on down in the rep questions, Mr. Houghton, there's
24 one that says, "Have we determined what another ideal carrier
25 for OP-1 is out there?" Do you see that one?

1 A. Yes.

2 Q. What efforts did you undertake to find carriers for OP-1?

3 A. Through the business development function, we were looking
4 at other products. I don't recall specifically targeting
5 looking for another carrier at that point in time. We were
6 looking at other products.

7 Q. In your view, was Calstrux a carrier for OP-1 at this
8 time?

9 A. We hoped it to be, yes.

04:19 10 Q. You hoped it to be in the future?

11 A. As an approved carrier, yes.

12 MR. LIBBY: Objection, your Honor.

13 THE COURT: Overruled.

14 MR. LIBBY: Leading.

15 THE COURT: Overruled.

16 BY MR. STERNBERG:

17 Q. What had to happen in order for Calstrux to be the carrier
18 of OP-1?

19 A. An FDA-approved clinical trial with statistically proved
04:19 20 results had to be undertaken.

21 Q. On the next page of Exhibit 115, Mr. Whitaker tells you
22 and other colleagues, "Unfortunately, there is nothing out
23 there that handles like Calstrux, and we're going to have to
24 recommend a product from another company."

25 What did you know before February 14, 2006 about the sales

1 force at Stryker Biotech recommending products to be mixed with
2 OP-1?

3 MR. LIBBY: Objection, your Honor.

4 THE COURT: Sustained.

5 BY MR. STERNBERG:

6 Q. Before February 14, 2006, Mr. Houghton --

7 A. Yes.

8 Q. -- what did you know about the manner in which OP-1 and
9 any other product -- whether it's Calstrux, Vitoss Flow, Isotis
04:20 10 OrthoBlast, or any other product -- were being promoted
11 together?

12 MR. LIBBY: Same objection, your Honor. Foundation.

13 THE COURT: Sustained.

14 BY MR. STERNBERG:

15 Q. When you got this email --

16 A. Yes.

17 Q. -- Exhibit 115, what was your reaction to Mr. Whitaker's
18 statement that, "Unfortunately, there is nothing out there that
19 handles like Calstrux, and we're going to have to recommend a
04:21 20 product from another company such as Vitoss Flow or Isotis
21 OrthoBlast II, as OP-1 by itself has too little volume and
22 doesn't handle well on its own"?

23 MR. O'CONNOR: Your Honor, just ambiguous on reaction.
24 What did he do?

25 THE COURT: Overruled. You may answer.

1 THE WITNESS: Well, we wanted to ensure that Calstrux
2 stand-alone and OP-1 reputation stood as it was. They both had
3 good reputations as products as stand-alone. And I was more
4 concerned about the damage that could be had by surgeons using
5 these two products together and having these adverse events,
6 that it could damage either or both of the products'
7 reputations as a stand-alone.

8 MR. LIBBY: Move to strike, your Honor.

9 THE COURT: Overruled -- or denied. It may stand.

04:22 10 BY MR. STERNBERG:

11 Q. Why were you concerned that the combination use of OP-1
12 and other products might damage the reputation of OP-1?

13 A. Well, until we'd done the correct trial and the correct
14 research to understand what the correct combination should be
15 of the two, you know, and then were able to put that on the
16 label so that the surgeons knew precisely how to do it, there
17 was too much variation; if surgeons chose to do it, they
18 were -- you know, the surgeon could do it in various different
19 ways. And so that could be -- you know, who knows what was
04:22 20 causing the problem.

21 MR. LIBBY: Move to strike, your Honor.

22 THE COURT: It may stand.

23 BY MR. STERNBERG:

24 Q. The next sentence says, "And to Pete's point, many
25 surgeons are just handed the product prior to implantation and

1 think it's all OP-1."

2 When you saw that, Mr. Houghton, what did you think?

3 MR. LIBBY: Objection, your Honor.

4 THE COURT: Sustained.

5 BY MR. STERNBERG:

6 Q. What concern did you have about a statement saying that
7 surgeons are handed something prior to implantation and think
8 it's all OP-1?

9 MR. LIBBY: Same objection, your Honor.

04:23 10 THE COURT: Sustained.

11 BY MR. STERNBERG:

12 Q. What discussions did you have after seeing this statement
13 with Ms. Alford or other people on your senior staff?

14 MR. LIBBY: Objection.

15 THE COURT: I think you'll have to --

16 MR. O'CONNOR: Foundation.

17 THE COURT: Because of the objection, I think you'll
18 have to point it to a topic.

19 BY MR. STERNBERG:

04:23 20 Q. Mr. Houghton, do you see the last sentence of the
21 paragraph we're looking at?

22 A. Yes.

23 Q. It says, "Many surgeons are just handed the product prior
24 to implantation and think it's all OP-1"?

25 A. Yes.

1 Q. On that specific point, the point that [as read] "many
2 surgeons are handed a product and think it's all OP-1," what,
3 if any, discussions did you have with your colleagues at
4 Stryker Biotech about that?

5 A. I don't recall having discussions with them on that
6 specific point. But we --

7 MR. O'CONNOR: Objection. End of answer, I think.

8 THE COURT: I think that probably is the answer.

9 We're at 1:00 o'clock. I think perhaps we should
04:24 10 pause at this point.

11 So jurors, we've begun the evidence. We'll break for
12 the weekend. It is a long weekend. Monday is a holiday,
13 Martin Luther King Day, so we will not sit on that day. So we
14 will resume on Tuesday morning at 9:00 a.m.

15 And again, please observe the direction to avoid any
16 discussion of the matter and the case. Enjoy the weekend and
17 we'll see you on Tuesday. We're in recess.

18 THE CLERK: All rise for the Court and the jury. The
19 Court will be in recess.

04:24 20 (The Court and jury exit the courtroom and there is a
21 recess in the proceedings at 1:02 p.m.)

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C E R T I F I C A T E

We, Marcia G. Patrisso, RMR, CRR, Official Reporter of the United States District Court, and Kimberly A. Smith, RDR, CRR, do hereby certify that the foregoing transcript constitutes, to the best of our skills and abilities, a true and accurate transcription of our stenotype notes taken in the matter of Criminal Action No. 09-10330-GAO, United States v. Stryker Biotech, et al.

/s/ Marcia G. Patrisso
MARCIA G. PATRISSE, RMR, CRR
Official Court Reporter

/s/ Kimberly A. Smith
KIMBERLY A. SMITH, RDR, CRR

Date: January 13, 2012